UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF OHIO
EASTERN DIVISION

IN RE NATIONAL PRESCRIPTION OPIATE LITIGATION	MDL 2804
	Case No. 17-md-2804
This document relates to:	Hon. Dan Aaron Polster
Track Three Cases	

PLAINTIFFS' RESPONSE IN OPPOSITION TO DEFENDANTS HBC SERVICE COMPANY AND GIANT EAGLE, INC.'S MOTION FOR SUMMARY JUDGMENT, AND, ALTERNATIVELY, PLAINTIFFS' SHOWING PURSUANT TO FEDERAL RULE OF CIVIL PROCEDURE 56(D) AND BRIEF IN SUPPORT

August 18, 2021

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I. INTRODUCTION

Defendants HBC Service Company ("HBC") and Giant Eagle, Inc. ("Giant Eagle" and, collectively with HBC, the "GE Defendants") claim they are entitled to summary judgment because: (1) they are entitled to "safe harbor" immunity; (2) there is no evidence they acted unlawfully or that they caused the public nuisance; and (3) as to its GERX distribution center, there is no evidence whatsoever supporting Plaintiffs' nuisance claim. The GE Defendants are wrong on all counts. First, they are not entitled to "safe harbor" immunity because there is ample evidence demonstrating that they have not fully complied with their statutory and regulatory obligations (including as it pertains to the GERX facility). The fact that they passed various DEA or Ohio Board of Pharmacy inspections does not establish their distribution and dispensing conduct was lawful; those inspections did not address whether the GE Defendants were implementing their SOM systems or controlled substance dispensing policies in accordance with the Controlled Substances Act ("CSA") or its implementing regulations. As for causation, the GE Defendants simply rehash the same arguments this Court has already rejected in Track One. Contrary to their assertions, there is sufficient evidence demonstrating that their distribution conduct (from both their HBC and GERX facilities) and their dispensing conduct was a substantial cause of the public nuisance in Lake and Trumbull Counties. The GE Defendants' summary judgment motion should be denied in its entirety.

Additionally and/or alternatively, Plaintiffs move the Court pursuant to Rule 56(d) of the Federal Rules of Civil Procedure to deny the GE Defendants' motion outright, or at a minimum, defer consideration of the motion, at least as it pertains to Plaintiffs' claims based on Giant Eagle's dispensing conduct, until Giant Eagle has completed its notes field production and Plaintiffs' experts have been given sufficient time to complete their analysis of that production. Whether

Giant Eagle documented its purported due diligence of red flag prescriptions in those notes fields is directly relevant to the question of whether it implemented effective controls against diversion as required under the CSA and its implementing regulations.

II. STATEMENT OF MATERIAL FACTS[1]

HBC, Giant Eagle's warehouse distribution center, distributed Schedule III controlled substances, including generic hydrocodone combination products ("HCPs"), to Giant Eagle pharmacies in Lake and Trumbull Counties (the "Counties") from November 2009 to October 2014. Dkt. #1968-3 (Millward Tr.) at 246:21 – 247:1. HBC stopped distributing Schedule III HCPs once the DEA reclassified those drugs to Schedule II. Dkt. #3027-32 (12/13/18 Tsipakis [HBC 30(b)(6)] Tr.) at 23:16-25. In early 2016, Giant Eagle opened a new warehouse, the Giant Eagle Rx Distribution Center ("GERX"), through which it began distributing Schedule II-V controlled substances, including opioids, to Giant Eagle pharmacies in the Counties. *Id*. at 80:18 – 81:7; Dkt. #1968-3 (Millward Tr.) at 34:21-25.

Giant Eagle operates over 200 pharmacies across Ohio, Pennsylvania, West Virginia, Maryland, and Indiana.[2] During the relevant time period, Giant Eagle operated between 12-14 pharmacies in the Counties. Ds' MOL, p. 3. Giant Eagle's pharmacies have dispensed Schedule II and Schedule III opioids to customers since at least the 1980s. Dkt. #3859-6 (3/8/21 Chunderlik Tr.) at 44:2-6.

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[1] Certain additional facts relevant to specific arguments are set forth in § IV below. Additionally, many of the purportedly "undisputed" facts set forth in the GE Defendants' motion are ultimately irrelevant to the resolution of that motion. To avoid wasting the Court's time on collateral issues, Plaintiffs have focused this opposition on the factual assertions that are actually relevant and material to the summary judgment arguments. Thus, the fact that Plaintiffs have not addressed a particular factual representation raised in the motion should not be construed as a concession that such representation is accurate or undisputed.

[2] Dkt. #3859-29 (Shaheen Tr.) at 73:12-21; Dkt. #3027-32 (12/13/18 Tsipakis [HBC 30(b)(6)] Tr.) at 154:1-2; Dkt. #3859-30 (3/17/21 Tsipakis [GE 30(b)(6)] Tr.) at 90:22 – 91:1.

A. HBC Failed To Maintain Effective Controls Against Diversion When Distributing Opioids from its Distribution Center.

From November 2009 through September 2014, HBC distributed over 3.5 million dosage units of Schedule III HCPs into Lake County, and over 7.4 million dosage units into Trumbull County. Dkt. #3852-10 (4/16/21 McCann Rep.) at pp. 39, 45. The facts demonstrating HBC's failure to maintain effective controls against diversion when distributing opioids during this time period have already been set forth at length in various briefs from the Track One cases, excerpts of which are attached hereto for the Court's convenience. *See* **Ex. 1** (CT1 Ps' Compliance MSJ [Dkt. #3015-1] Excerpts) at pp. 132-139; **Ex. 2** (CT1 Ps' Opp. to HBC MSJ [Dkt. #3009-1]) at pp. 1-6; **Ex. 3** (CT1 Ps' Causation MSJ Opp. [Dkt. #3002-1] Excerpts) at pp. 23-24; **Ex. 4** (CT1 Ps' Compliance MSJ Reply [Dkt. #3017-1] Excerpts) at pp. 50-52. In the interest of brevity and to avoid repetition, Plaintiffs incorporate by reference the factual assertions from these briefs, including all relevant exhibits, as if full set forth herein.

B. Giant Eagle Failed To Maintain Effective Controls Against Diversion When Distributing Opioids from its GERX Distribution Center.

When Giant Eagle opened its GERX facility in 2016, it made minimal revisions to its already existing "Inventory Control – Suspicious Order Policy."[3] Under this policy, orders above a specified threshold were flagged on a daily threshold report.[4] But until early 2017, the thresholds

[3] Dkt. #3027-32 (12/13/18 Tsipakis [HBC 30(b)(6)] Tr.) at 77:12 – 80:16; **Ex. 5** (12/13/18 Tsipakis Dep. Ex. 12) at HBC_MDL00004386-4387.

[4] Dkt. #3027-32 (12/13/18 Tsipakis [HBC 30(b)(6)] Tr.) at 131:6-9, 134:11 – 135:3; **Ex. 5** (12/13/18 Tsipakis Dep. Ex. 12) at HBC_MDL00004386; Dkt. #1959-24 (1/16/19 Chunderlik Tr.) at 202:8-15 ("Q:… The only automated process that existed at this time in April of 2016 were the daily threshold reports that Kayla Voelker was creating where if a store's order exceeded the threshold, it would trigger and pop up on the daily report? A: That's correct.") (internal objection omitted); *see also id.* at 201:18 – 202:4 (acknowledging that orders of unusual pattern or frequency "wouldn't be part of what shows up from an automated algorithm triggering the order").

were set at 3 times the rolling 12 month *chain-wide* average for a given chemical/ingredient.[5] In other words, each store was measured according to a chain-wide average regardless of a particular pharmacy's ordering history, frequency, or the population it served.[6] Giant Eagle has admitted that using such a chain-wide threshold is "flawed" and can lead to false negatives.[7]

Giant Eagle continued to utilize a chain-wide threshold at its GERX facility for at least a year. Dkt. #3027-32 (12/13/18 Tsipakis [HBC 30(b)(6)] Tr.) at 167:14 – 168:2. Notably, at the same time it was using this inadequate threshold system, it was assuring at least one business partner that its SOM system: (i) was an "automated" process; (ii) "uses algorithms to identify controlled substance orders that require investigation before releasing the order for distribution[;]" (ii) monitors individual customers based on "Order Frequency" and "Order Pattern[;]" and (iii) "generates flags based on . . . characteristics specific to pharmacy location . . ." **Ex. 7** (P-HBC-1024) at HBC_MDL00030064-0065, 0067-0069. Unsurprisingly, it refused to provide that partner with a copy of its SOM policy to substantiate these misleading (or outright false) representations.[8]

In actuality, Giant Eagle systematically ignored its threshold reports and continued to ship

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[5] Dkt. #3027-32 (12/13/18 Tsipakis [HBC 30(b)(6)] Tr.) at 135:4-23 ("Q: So from 2013 through 2017, it was a chain-wide Giant Eagle-wide threshold average? A: Looking at our stores in totality as a chain and then applying that threshold, the chain average, to each location, yes."), 150:23 – 151:2, 167:14-18, 255:24 – 256:2; **Ex. 6** (12/13/18 Tsipakis Dep. Ex. 22) at HBC_MDL00046225 (11/16 internal document noting that "[t]he current state utilizes a static threshold that is established across all stores by product").

[6] Dkt. #3027-32 (12/13/18 Tsipakis [HBC 30(b)(6)] Tr.) at 135:24 -136:3, 143:14 – 144:13, 155:10-15.

[7] Dkt. #3027-32 (12/13/18 Tsipakis [HBC 30(b)(6)] Tr.) at 155:5-9, 166:1-3, 166:11-17 ("I would agree with you it's probably flawed and it could be done better[.]"), 167:14-17, 247:21 – 248:3 ("Q:…. [W]ould you agree that while using a chain-wide threshold can lead to false positives for some stores, could it also lead to false negatives or a sense of reassurance for some stores that may actually be using or ordering a lot more of a hydrocodone product than it normally would? A: It's possible.").

[8] *Id*. at 0064 ("I marked NO for the question that asked if we would be willing to send a copy of our documented SOM business practice. They may balk at that."), 0068. *See also* Dkt. #1959-24 (1/16/19 Chunderlik Tr.) at 204:4-7.

opioids to pharmacies that exceeded the thresholds. One report from October 2016 shows 183 orders exceeding the thresholds in that month alone (with some orders as much as 3x or 10x the thresholds).[9] That same report shows that *eleven* Giant Eagle pharmacies in the Counties were flagged as exceeding the thresholds during that one month.[10] For example, during that time period, Giant Eagle had a chain-wide threshold of 4,895 for generic hydrocodone; this threshold was already 3 times the monthly average of the rolling 12-month period nationwide.[11] Yet Giant Eagle shipped *21,500* units of generic hydrocodone to a single pharmacy in Trumbull County (Pharmacy #1405) that month.[12] Notably, the GE Defendants never reported even one suspicious order from its stores in the Counties to the DEA.[13]

Additionally, until at least early 2017, Giant Eagle's threshold system did not block orders, but rather flagged orders that were "in process of shipping or having been shipped."[14] Giant Eagle

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[9] **Ex. 8** (12/13/18 Tsipakis Dep. Ex. 14); Dkt. #3027-32 (12/13/18 Tsipakis [HBC 30(b)(6)] Tr.) at 138:21 – 140:18, 142:12 – 143:13, 146:8-20, 150:2-11, 153:10 – 156:15. Although the report mistakenly lists the HBC distribution facility as the vendor instead of GERX, HBC confirmed that "in 2016, all of the drugs would be coming from [GERX]." Dkt. #3027-32 (12/13/18 Tsipakis [HBC 30(b)(6)] Tr.) at 144:14 – 145:10.

[10] **Ex. 8** (12/13/18 Tsipakis Dep. Ex. 14) (showing Pharmacies #216, 1217, 1405, 1419, 1435, 4002, 4051, 4056, 4097, 6377, and 6381 exceeding threshold in 10/16); **Ex. 9** (Shaheen Dep. Ex. 2) at pp. 2-5 (Pharmacies #1405, 1419, 1435, 4002, 4051, and 4056 are in Trumbull County; Pharmacies #216, 1217, 4097, 6377, and 6381 are in Lake County); Dkt. #3859-29 (Shaheen Tr.) at 78:1-17.

[11] **Ex. 8** (12/13/18 Tsipakis Dep. Ex. 14) at p. 1; Dkt. #3027-32 (12/13/18 Tsipakis [HBC 30(b)(6)] Tr.) at 135:4-7.

[12] **Ex. 8** (12/13/18 Tsipakis Dep. Ex. 14) at p. 1; Dkt. #3027-32 (12/13/18 Tsipakis [HBC 30(b)(6)] Tr.) at 155:21 – 156:7.

[13] Indeed, despite repeated orders exceeding the thresholds, the GE Defendants have only ever reported two suspicious orders to the DEA, neither of which came from the Counties or involved an opioid at issue in this litigation. Dkt. #1959-24 (1/16/19 Chunderlik Tr.) at 246:17 – 247:12; Dkt. #3027-32 (12/13/18 Tsipakis [HBC 30(b)(6)] Tr.) at 181:9-16, 183:2-20, 185:2 – 186:11, 188:1-12, 197:4 – 199:14, 309:14-20; Dkt. #3852-13 (Rafalski Rep.) at p. 157.

[14] Dkt. #3027-32 (12/13/18 Tsipakis [HBC 30(b)(6)] Tr.) at 136:6-14. *See also id.* at 172:18-25, 173:10-14, 174:15-23, 213:8-11 ("Q: So in March of 2016, HBC or Giant Eagle, their current system would not physically stop the orders that rose above the threshold; correct? A: Correct."); **Ex. 6** (12/13/18 Tsipakis Dep. Ex. 22) at HBC_MDL00046225, 6227 (in 11/16, proposing to implement tool that "will provide GE with the ability to block orders that exceed the set threshold . . ." with proposed deployment in 2/17).

has admitted that all orders listed on the threshold report were shipped and none were ever recalled; thus, no pre-shipment due diligence occurred with these flagged orders.[15] Notably, in March 2016, Giant Eagle had the opportunity for its GERX facility to utilize a third-party system to stop over-threshold orders from shipping, but its Senior Pharmacy Director declined, claiming it was not worth the expense because the "only thing [the new system] did that our current system would not do, was stop the orders physically if there was a threshold."[16] Instead, Giant Eagle waited until early 2017 to develop a system to stop orders that hit the threshold.[17]

Moreover, although Giant Eagle's internal policies stated that the GERX facility was to document and retain the records of any investigations and their outcome,[18] Giant Eagle admits that it did not even develop a system for entering investigative notes and information regarding flagged orders until 2017.[19] Additionally, any due diligence investigations that took place would only occur once for a store for the month, even if the store continued to order controlled substances above the threshold amounts.[20] Thus, Giant Eagle allowed pharmacies which exceeded the triple

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[15] Dkt. #3027-32 (12/13/18 Tsipakis [HBC 30(b)(6)] Tr.) at 171:25 – 172:4, 174:15-23, 175:3-18, 176:3-14.

[16] **Ex. 10** (12/13/18 Tsipakis Dep. Ex. 20) at HBC_MDL00028498 (also noting the proposed system "would benchmark against other retailer"); Dkt. #3027-32 (12/13/18 Tsipakis [HBC 30(b)(6)] Tr.) at 212:17 – 214:14.

[17] Dkt. #3027-32 (12/13/18 Tsipakis [HBC 30(b)(6)] Tr.) at 215:6-25.

[18] **Ex. 5** (12/13/18 Tsipakis Dep. Ex. 12) at HBC_MDL00004387 (2016 policy stating "GERXDC retains the records of the investigation and outcome for six (6) years"), 00045917 (2/17 policy stating that "[t]he documentation of the review and investigation process must be retained in readily retrievable form according to the Giant Eagle Document Retention Policy and not less than two years").

[19] Dkt. #3027-32 (12/13/18 Tsipakis [HBC 30(b)(6)] Tr.) at 162:9-24, 163:16-24 (stating that prior to early 2017, the GE Defendants had "no central repository" for due diligence records). *See also* Dkt. #1959-24 (1/16/19 Chunderlik Tr.) at 220:13-20 ("Q: What is a case management process? A: Having a record of basically what was done to – the steps taken to investigate a situation. Q: And that wasn't something, as we've talked about, that occurred up till this point in November of 2016; right? A: Correct."), 241:1-5, 241:10-20 ("Q: [Prior to January 2017,] [t]here wasn't a repository or database or some centralized location where investigative files were kept in the past? A: Correct, yes.").

[20] Dkt. #3027-32 (12/13/18 Tsipakis [HBC 30(b)(6)] Tr.) at 157:19 – 158:11. *See also* **Ex. 11** (P-09693) at 0001 ("This value was a monthly accumulation that reset the first of each month which mirrored McKesson's system

threshold to continue to exceed the threshold with subsequent orders without any additional scrutiny until the end of the month. *Id*.

Significantly, in late November 2016, Giant Eagle internally acknowledged the deficiencies of its SOM program: "It is the belief of the business that Giant Eagle's suspicious order monitoring is 75 to 85 percent of where it needs to be."[21] Giant Eagle recognized that certain steps must be taken to achieve "[t]he missing 15 to 25 percent of the necessary functionality *needed to bring Giant Eagle into full compliance with CFR 1301.74(b)*[.]"[22] Thus, Giant Eagle itself admits that, both prior to the opening of the GERX facility and from February 2016 (when GERX began distributing Schedule II & III controlled substances) until at least February/March 2017 (when it revised its SOM policies further),[23] its SOM program did not fully comply with CSA regulations. Significantly, during that year, Giant Eagle's GERX facility distributed almost 2 million dosage units of opioids into the Counties.[24]

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but left big holes in our logic. . . . This form expired at the end of each month (again a problem).").

[21] **Ex. 6** (12/13/18 Tsipakis Dep. Ex. 22) at HBC_MDL00046224; *see also* Dkt. #3027-32 (12/13/18 Tsipakis [HBC 30(b)(6)] Tr.) at 229:12-17, 230:5-12. Additionally, in May 2016, Giant Eagle internally acknowledged that it "[did not] believe [its SOM worksheet] will be functional for the central signers." **Ex. 12** (P-HBC-1026) at HBC_MDL00047152.

[22] **Ex. 6** (12/13/18 Tsipakis Dep. Ex. 22) at HBC_MDL00046224 (emphasis added).

[23] In February and March of 2017, Giant Eagle created its "Order Monitoring System Policy" which, among other things, (i) added the use of an algorithm to identify suspicious orders, (ii) blocked orders in excess of threshold limits, and (iii) added four potential levels of review for blocked orders to be investigated prior to either being released to the pharmacy or reported as suspicious. **Ex. 5** (12/13/18 Tsipakis Dep. Ex. 12) at HBC_MDL00045916-5917, 00051908, 00043414. Notably, Giant Eagle testified that the information used to create the 2017 SOM system was always available at Giant Eagle, though not previously incorporated into its SOM policies. Dkt. #3027-32 (12/13/18 Tsipakis [HBC 30(b)(6)] Tr.) at 88:15-20, 88:24 – 90:11, 104:12-22, 107:12-23, 222:20 – 223:25, 225:3-22, 258:22 – 259:21.

[24] **Ex. 13** (McCann Rep. Appx. 10 Excerpts) at pp. 47, 426, 475.

C. GIANT EAGLE FAILED TO MAINTAIN EFFECTIVE CONTROLS AGAINST DIVERSION WHEN DISPENSING OPIOIDS FROM ITS PHARMACIES.

1. Giant Eagle's policies regarding the dispensing of controlled substances were untimely and inadequate.

As a registrant licensed to dispense controlled substances pursuant to the CSA, Giant Eagle knew and understood its statutory and regulatory obligations related to the dispensing of opioids.[25] Giant Eagle also knew and understood the dangerous nature of opioids and risks that such drugs could be diverted.[26] Yet despite this knowledge, and despite its awareness of the worsening opioid crisis,[27] Giant Eagle did not implement written procedures for controlled substance dispensing until mid-2013.[28]

In June 2013, Giant Eagle's compliance department drafted a detailed 47-page "Giant Eagle Pharmacy Controlled Substances Manual" (the "Manual") containing approximately 20 pages on dispensing red flags and due diligence in order to address what Giant Eagle recognized

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[25] Dkt. #3859-30 (3/17/21 Tsipakis [GE 30(b)(6)] Tr.) at 10:3 – 11:12, 34:1-15, 35:1 – 36:19, 77:13-21, 110:1 – 112:4, 113:23 – 115:9, 179:13-18; **Ex. 14** (3/17/21 Tsipakis Dep. Ex. 2) at HBC_MDL00032657; Dkt. #3027-32 (12/13/18 Tsipakis [HBC 30(b)(6)] Tr.) at 260:2-14; Dkt. #3859-29 (Shaheen Tr.) at 380:5-12; Dkt. #3859-28 (6/11/21 Rafalski Tr.) at 430:23 – 431:5; Dkt. #3859-4 (6/15/21 Catizone Tr.) at 332:23 – 333:21; **Ex. 15** (Mooney Dep. Ex. 1 Excerpts) at HBC_MDL00190723 ("One of our responsibilities in pharmacy is to try and limit the sale of drugs for illegal or abusive use."); Dkt. #3859-2 (Ashley Tr.) at 113:15 – 117:21.

[26] Dkt. #3859-29 (Shaheen Tr.) at 380:5 – 383:5; **Ex. 14** (3/17/21 Tsipakis Dep. Ex. 2) at HBC_MDL00032655; Dkt. #3859-6 (3/8/21 Chunderlik Tr.) at 31:4-14; **Ex. 16** (3/8/21 Chunderlik Dep. Ex. 2) at pp. 14-15; **Ex. 15** (Mooney Dep. Ex. 1 Excerpts) at HBC_MDL00190725; Dkt. #1959-18 (Carlson Tr.) at 100:12-17.

[27] Dkt. #3859-6 (3/8/21 Chunderlik Tr.) at 29:15-21 ("Q:…. You were the manager of pharmacy training for about four or five years, from '08 to 2012, and you already told us that you understood during that time period that there was an opioid epidemic throughout the country, correct? A: Yes."), 30:16-20; **Ex. 14** (3/17/21 Tsipakis Dep. Ex. 2) at HBC_MDL00032655; Dkt. #3859-30 (3/17/21 Tsipakis [GE 30(b)(6)] Tr.) at 169:24 – 170:1, 171:23 – 172:14; **Ex. 16** (3/8/21 Chunderlik Dep. Ex. 2) at pp. 14-15; Dkt. #1959-1 (Bencivengo Tr.) at 54:23 – 55:12; Dkt. #1959-18 (Carlson Tr.) at 115:24 – 116:5.

[28] Dkt. #3859-30 (3/17/21 Tsipakis [GE 30(b)(6)] Tr.) at 30:18-22, 31:24 – 32:16, 33:13-20, 40:4-15, 41:9-17. *See also* Dkt. #3859-6 (3/8/21 Chunderlik Tr.) at 160:11-22 (Giant Eagle's first written drug utilization review (DUR) policy created in 4/17), 161:21 – 162:21 (DUR policy not specific to opioids). Prior to 2013, Giant Eagle claims its "guidelines" mirrored the requirements of the CSA and were communicated verbally to pharmacists during meetings and conference calls. Dkt. #3859-30 (3/17/21 Tsipakis [GE 30(b)(6)] Tr.) at 28:8-22, 30:23 – 31:9, 35:8 – 36:8.

as the "epidemic" created by the "abuse of prescription drugs." **Ex. 14** (3/17/21 Tsipakis Dep. Ex. 2). The draft Manual breaks out red flags and prescription due diligence steps applicable to each stage of the prescription fill process, and for each pharmacy employee who might be involved in filling the prescription. *Id*. at HBC_MDL00032655, 2658, 2662-2672. Giant Eagle acknowledged in the Manual that "[i]t is our responsibility both as a company and as healthcare professionals to do all we can to curb the misuse of prescription drugs." *Id*. at 2655.[29]

Incredibly, Giant Eagle *never* implemented this policy and never provided the Manual to its pharmacies or pharmacists.[30] Instead, Giant Eagle chose to implement a four-page "Controlled Substance Dispensing Guideline" (the "Guidelines") with significantly less detail and instruction.[31] When asked why it failed to provide the detailed Manual to its pharmacists, Giant Eagle conceded that "consolidat[ing] and put[ting] things together in one place" for the pharmacists would be "helpful," but claimed it "also would give [them] a false sense of security that this is the only document and this is the only thing you should be looking at." Dkt. #3859-30 (3/17/21 Tsipakis [GE 30(b)(6)] Tr.) at 177:7-12. Instead, Giant Eagle claimed it would be better for its pharmacists to pick up on the information bit by bit, from sources including continuing education, staff meetings, the Giant Eagle intranet, and emails. *Id*. at 177:13-19, 179:1-9. Despite these claims, controlled substance dispensing does not appear to have been a primary focus of its training efforts.[32]

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[29] *See also* **Ex. 16** (3/8/21 Chunderlik Dep. Ex. 2) at p. 16 (internal GE powerpoint acknowledging same).

[30] Dkt. #3859-30 (3/17/21 Tsipakis [GE 30(b)(6)] Tr.) at 161:2-19 ("[T]his document was an internal draft that our compliance department was working on that never got published or distributed outside of the compliance department."), 162:5-10, 163:1-10, 178:14-17; Dkt. #3859-31 (5/5/21 Tsipakis [GE 30(b)(6)] Tr.) at 230:3-10.

[31] **Ex. 17** (3/17/21 Tsipakis Dep. Ex. 1); Dkt. #3859-30 (3/17/21 Tsipakis [GE 30(b)(6)] Tr.) at 161:16-19 ("[T]he Controlled Substance Guidelines document is what was published and used for the stores, not [the Manual]."), 182:1-15.

[32] *See, e.g.,* Dkt. #1968-5 (Mollica Tr.) at 34:6-9 ("Q: Was there anyone within Giant Eagle that was focused

2. Giant Eagle failed to provide its pharmacists with the necessary tools and information to be able to exercise their corresponding responsibility.

In addition to withholding the detailed 47-page Manual from its pharmacists, Giant Eagle also failed to provide them with the tools, guidance, data, and resources necessary to properly exercise their corresponding responsibility. Giant Eagle acknowledges that it is obligated "to make sure that [its] pharmacists have the tools that they need to be able to do their job."[33] Although Giant Eagle claims to have provided "the tools necessary for [its] pharmacists to be able to use their professional judgment[,]"[34] the evidence demonstrates otherwise.

Giant Eagle recognizes that its pharmacists "need to assess the information that they have in front of them at the time of dispensing" when deciding "whether to fill or not fill a prescription." Dkt. #3859-30 (3/17/21 Tsipakis [GE 30(b)(6)] Tr.) at 14:17-20. Giant Eagle had access to extensive dispensing data that would identify patterns, trends, and problematic prescribers potentially involved in diversion.[35] Yet, as discussed below, it failed to provide its pharmacists with the tools necessary to utilize all of this data at the store level *prior to filling* a prescription.

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specifically on training pharmacists to avoid diversion of controlled substances? A: No."); *see also id.* at 32:2-14 ("There's not a requirement to do controlled substance training inside a pharmacy. We did generalized training of which controlled substances would in cases be parts of that, CBTs, things like that."), 49:17 – 50:3; Dkt. #3859- 6 (3/8/21 Chunderlik Tr.) at 32:10 – 33:4 ("I can't say that I used the opioid epidemic specifically to – in training to talk about that specifically in relation to any training in regards to controlled substance dispensing.").

[33] Dkt. #3859-30 (3/17/21 Tsipakis [GE 30(b)(6)] Tr.) at 77:19-21; *see also id.* at 14:3-6, 179:13-18 ("Q: You agree that Giant Eagle was obligated to have a system in place to prevent against diversion, correct? A: Giant Eagle is obligated to have safeguards to help prevent diversion, yes.").

[34] Dkt. #3859-30 (3/17/21 Tsipakis [GE 30(b)(6)] Tr.) at 13:6-9.

[35] *See, e.g., id.* at 67:23 – 68:9, 139:10-22, 141:9-14; Dkt. #3859-2 (Ashley Tr.) at 132:16 – 134:17; Dkt. #3852-9 (4/15/21 Malone Rep.) at pp. 4-8; **Ex. 18** (P-09523) at 002-003 (2016 memo reflecting ability to "[u]se the data warehouse to find out the doctor's prescribing habits across the GE brand' and the ability to use both the data warehouse and "EPS to research the doctor's patients"; same memo suggests Giant Eagle had a variety of geographically-based investigative tools including the doctor zip code in relation to his or her patients' zip codes and in relation to that pharmacy).

Giant Eagle points to the fact that it provided its pharmacists with internet access, enabling them to consult state PDMP databases. Dkt. #3859-30 (3/17/21 Tsipakis [GE 30(b)(6)] Tr.) at 27:10-18, 108:14-24, 141:3-8.[36] Since October 2006, Ohio has made its PDMP, the Ohio Automated Rx Reporting System ("OARRS") program, available to pharmacists as a tool to use to detect and prevent controlled substance misuse and diversion. Dkt. #3852-3 (5/19/21 Catizone Supp. Rep.) at pp. 16-18, 20. Despite its limitations,[37] OARRS provides important information about a patient's prescription history that assists pharmacists in identifying patients who may be misusing prescription opioids.[38]

Incredibly, instead of requiring its pharmacists to access the PDMP every time they were asked to fill prescriptions for controlled substances, Giant Eagle instructed its pharmacists that they "must have cause before accessing the PDMP[,]"[39] and that if they did access the PDMP, they must "note the date and reason for accessing the database." **Ex. 17** (3/17/21 Tsipakis Dep. Ex. 1) at HBC_MDL00191293-1294.[40] Some red flags, however, may not be apparent unless and until

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[36] PDMPs, or Prescription Drug Monitoring Programs, are statewide electronic databases which contain dispensing information on controlled and non-controlled substances that state boards of pharmacy require be submitted to the database when such substances are dispensed. Dkt. #3852-3 (5/19/21 Catizone Supp. Rep.) at p. 16.

[37] PDMPs, while extremely helpful for providing patient-specific data, do not provide pharmacists with the information they need to identify and resolve prescriber-specific red flags. Dkt. #3859-21 (Mooney Tr.) at 219:21 – 220:3, 221:6 – 222:11.

[38] Dkt. #3852-3 (5/19/21 Catizone Supp. Rep.) at pp. 16-18, 20; Dkt. #3859-5 (6/16/21 Catizone Tr.) at 477:2-14; Dkt. #3859-2 (Ashley Tr.) at 132:7-10; Dkt. #3859-30 (3/17/21 Tsipakis [GE 30(b)(6)] Tr.) at 56:5-11 (acknowledging usefulness of PDMPs).

[39] Despite these instructions, there is evidence that Giant Eagle's pharmacists in the Counties were not consistently accessing OARRS even when presented with red flags. Dkt. #3859-9 (Edwards Tr.) at 187:6 – 189:12 (Ohio BOP inspection uncovered evidence of improper dispensing; "I believe that pharmacist was either not even signed up for OARRS or never ran OARRS reports. So that was – that was kind of a big deal. . . . In my mind, I remember him not ever running OARRS reports[.]"); Ds' SJ-Ex. 11 at pp. 72 (Ohio BOP finding that Lake County pharmacist failed to run OARRS despite awareness of therapeutic duplication associated with controlled substance prescription), 240 (Ohio BOP finding that "no OARRS report was noted to have been accessed"). (Note: Because the GE Defendants' SJ-Ex. 11 is 738 pages and the bates-numbers are not in order, Plaintiffs' refer to the specific pages of the overall PDF (*e.g.*, p. 72 out of 738)).

[40] In 2015, Ohio began to mandate that pharmacists review OARRS data before dispensing certain drugs, including

the pharmacist consults the PDMP. For example, if a patient was filling opioid prescriptions at multiple different chain pharmacies (*e.g.*, Giant Eagle, Walgreens, and CVS), that would likely not be immediately apparent to the pharmacist upon receipt of the prescription. That information typically could only be found in the PDMP data.[41]

Giant Eagle also states that its pharmacists have access to certain dispensing data, patient profiles, and hardcopy prescriptions, and have the ability to call prescribers and other Giant Eagle stores for additional information.[42] But Giant Eagle pharmacists only had direct access to dispensing data for their individual stores,[43] precluding them from running chain-wide reports to identify certain red flags, such as pattern prescribing.[44] As for the patient profiles, hardcopy

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all federally scheduled controlled substances. Dkt. #3852-3 (5/19/21 Catizone Supp. Rep.) at p. 19; Dkt. #3859- 5 (6/16/21 Catizone Tr.) at 466:1-6.

[41] Dkt. #3859-4 (6/15/21 Catizone Tr.) at 275:16-20 ("If those prescriptions were prescribed by prescribers outside of that pharmacy chain or they were filled at pharmacies outside of that pharmacy chain, that information would not be available to the pharmacist unless they queried the PDMP."); Dkt. #3859-30 (3/17/21 Tsipakis [GE 30(b)(6)] Tr.) at 56:5-11, 67:9-12 ("OARRS would be used to get information on what controlled substances, if any, were filled by another pharmacy for that patient.").

[42] Dkt. #3859-30 (3/17/21 Tsipakis [GE 30(b)(6)] Tr.) at 108:14-24, 141:3-8, 144:13 – 145:8.

[43] And even that data was limited. *See, e.g.,* Dkt. #3859-21 (Mooney Tr.) at 82:11 – 83:2 (physician's specialty not tracked within Giant Eagle software system), 83:3 – 84:3 (number of prescriptions a particular doctor had written that had been filled at individual pharmacy or chain-wide was not information ever made available to her) (corrected by errata), 85:6 – 86:1 (dispensing platform did not provide alerts or information about disciplinary actions pending or adjudicated against a physician); **Ex. 19** (Errata to Mooney Tr.) (correcting p. 83, line 11); Dkt. #3859-20 (Miller [GE 30(b)(6)] Tr.) at 89:24 – 90:6, 195:25 – 196:6 ("Q:…. How do you – how do I pull DURs for specific prescribers out of the printout version? A: Other than accessing the printout version for prescriptions written by that provider, that's [sic] no report to show DURs tied to a prescriber."), 202:23 – 206:22; Dkt. #3859-6 (3/8/21 Chunderlik Tr.) at 134:13-23, 138:1 – 139:3 ("Q:…. [I]s there any type of alert, kind of like what you told us about with the early refills, an alert or a pop-up or a message that tells that pharmacists about other pharmacists who have not filled prescriptions for that particular doctor? Was that something that happens within the Giant Eagle system? A: As I recall, not necessarily. Q: Well, it's not – really not necessarily. It's no, that that does not happen, correct? . . . . A: Not that I can recall.") (internal objections omitted); Dkt. #1968-5 (Mollica Tr.) at 35:11-19 ("Q: Was there any log or report that was kept by Giant Eagle to indicate when pharmacists had flagged or denied prescriptions to patients? A: We had monthly audits of controlled substances, but reports where pharmacists had to make medical decisions as to whether to dispense, I'm not aware of any reports that were specific to that.") (internal objection omitted).

[44] *See, e.g.,* Dkt. #3859-30 (3/17/21 Tsipakis [GE 30(b)(6)] Tr.) at 50:15 – 51:10 (pharmacists did not have ability to run reports on all "prescriptions by a physician" across all Giant Eagle stores), 52:18 – 54:5 ("Q: A pharmacist could not analyze the patterns of a prescriber in relation to opiate cocktails across all Giant Eagle stores, correct?

prescriptions, and information obtained by calling prescribers or other stores, such information was only helpful to the extent pertinent information had been documented.

Giant Eagle recognizes the importance of documenting due diligence.[45] But although its abbreviated Guidelines instructed its pharmacists to "document the steps they have taken to verify questionable prescriptions, including any calls to the prescriber, conversations with the patient, medication history review, and notate on the prescription itself or in the computer system utilizing appropriate note fields[,]"[46] Giant Eagle did not enforce this documentation policy. Instead, it gave its pharmacists the discretion as to whether or not to document due diligence.[47] And, prior to 2013/2014, any documentation of due diligence was typically done on the hard copy prescriptions, which were not scanned into the computer at that time.[48] This made accessing that

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A: An individual store couldn't run a report like that."), 55:23 – 56:4 ("Q:…. Can a pharmacist or any pharmacy employee at Giant Eagle run a report at the store level to look at a prescriber's pattern of prescribing cocktails to patients across all Giant Eagle stores? A: At the store level they cannot."), 59:24 – 60:2 ("As I've previously stated, at the store level they can't run a global report for multiple prescribers or multiple stores."), 61:2-4, 103:23 – 104:5, 109:3-9, 137:24 – 138:12, 139:10-22, 141:3-14; Dkt. #3859-20 (Miller [GE 30(b)(6)] Tr.) at 171:3-9.

[45] Dkt. #3859-30 (3/17/21 Tsipakis [GE 30(b)(6)] Tr.) at 143:1-22, 151:24 – 152:4 ("Q: And the reason for documenting . . . due diligence is at least in part to help communicate information amongst pharmacists at Giant Eagle, correct? A: Correct."); **Ex. 16** (3/8/21 Chunderlik Dep. Ex. 2) at p. 19 (internal GE powerpoint stating to "DOCUMENT! DOCUMENT! DOCUMENT!!!!" due diligence).

[46] **Ex. 17** (3/17/21 Tsipakis Dep. Ex. 1) at HBC_MDL00191294; Dkt. #3859-30 (3/17/21 Tsipakis [GE 30(b)(6)] Tr.) at 142:14-24, 151:2-23.

[47] Dkt. #3859-30 (3/17/21 Tsipakis [GE 30(b)(6)] Tr.) at 146:13 – 147:2 ("Q:…. I said, does Giant Eagle require that notes on the back of prescriptions be scanned into the system? . . . . A: There's discretion there, yes."), 149:17-18 (claiming "[n]ot all red flags require documentation or for it to be written out"); Dkt. #1968-5 (Mollica Tr.) at 35:20-22 ("Pharmacists could make notes on patient profiles if they felt there was diversion issues and flag things in the system."); *see also id.* at 125:10-19 ("Q: Did Giant Eagle keep any documentation where we could determine whether or not there were ever instances where Giant Eagle pharmacists did not fill all prescriptions written by a doctor? A:. . . . There's no regulatory requirement to track what you didn't fill.") (internal objection omitted); Dkt. #1959-24 (1/16/19 Chunderlik Tr.) at 252:6-10 (not aware of any log or repository where one could look to "try to figure out within Giant Eagle how many of the pharmacists decided not to fill prescriptions"), 253:8-11.

[48] Dkt. #3859-21 (Mooney Tr.) at 135:5-13 ("[S]o with our previous system, before we were able to scan hard copies into the computer system, any time we had a question on a prescription, any time we spoke with a doctor's office, with a pharmacy, we didn't – you know, those note fields in our old system weren't there. All of our documentation was done on the prescription itself. So we would make notes all over those prescriptions."), 135:23 – 136:4 ("Q: Okay. At what point in time did the system change to where you were able to scan and upload hard

due diligence difficult and time-consuming.[49]

Aside from OARRS, on those occasions when its pharmacists had cause to consult it, and whatever information may have been documented in the patient profile, Giant Eagle essentially expected its pharmacists to rely on their memories to identify red flags of diversion. According to Giant Eagle, its pharmacists know their customers and the prescribers in the community.[50] But Giant Eagle's pharmacies averaged thousands of prescriptions a week, with some of the busier stores receiving as many as 6,000 prescriptions a week.[51] Moreover, Giant Eagle often utilized "floater pharmacists," who worked in multiple stores, some located up to an hour away.[52]

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copy prescriptions. A: Somewhere around 2013, '14 maybe is when we got the new prescription system, the new – our new pharmacy system."); *see also* Dkt. #1968-5 (Mollica Tr.) at 36:16-23 ("Q: So between 2007 and 2014, if I wanted to try to figure out how many times a Giant Eagle retail pharmacist had flagged a patient for suspicious of diversion, how would I go about doing that? A: I don't know that you could.") (internal objection omitted).

[49] Hardcopy prescriptions were filed in folders within boxes kept at the individual store. Dkt. #3859-21 (Mooney Tr.) at 278:20 – 279:5, 279:13-22; Dkt. #3859-20 (Miller [GE 30(b)(6)] Tr.) at 81:18-24, 254:9-21. To access the notes from those prescriptions, the pharmacist would physically have to pull them from the box. Dkt. #3859-20 (Miller [GE 30(b)(6)] Tr.) at 193:14-21. And if the prescriptions had been filled at another Giant Eagle location, the pharmacist would have to take the extra step of calling that store and asking someone there to physically pull it. *Id*. at 257:10-22 ("Q:…. What I asked was, is that a new prescription that was questionable, presented to a pharmacist at Giant Eagle X, that pharmacist would not have access to notes taken by another pharmacist at another Giant Eagle if they're recorded in hard copy when answering questions and questionable prescriptions in regards to opiates. Correct? A:…. [T]hey would not have access to the documented notes."), 258:16-18 (noting that "in theory [the pharmacist] could call that other location to look at any notes on the hard copy").

[50] Dkt. #3859-30 (3/17/21 Tsipakis [GE 30(b)(6)] Tr.) at 128:15 – 129:3, 135:15 – 136:9 (stating its pharmacists "know the prescriptions that come in, they know the prescribers that are in the area, they know what the prescribing habits are for those areas"), 138:22 – 139:2.

[51] Dkt. #3859-30 (3/17/21 Tsipakis [GE 30(b)(6)] Tr.) at 91:2-4, 130:12-23 ("Q:…. So you testified earlier some of the busier stores do approximately 6,000 prescriptions a week, correct? A: We have some stores that are that busy, yes. Q: So that's approximately 8 or 900 prescriptions per day, correct? A: Roughly, yes. Q: So again, roughly, 60, 70, 80 prescriptions in an hour at the busiest stores, correct? A: Correct."), 140:21-24 (noting "average store volume is 2,300 per week"). *See also* **Ex. 15** (Mooney Dep. Ex. 1 Excerpts) at HBC_MDL00190692 (internal Giant Eagle manual for pharmacy technicians stating: "Most of our pharmacies are very busy and sometimes hectic places.").

[52] Dkt. #3859-21 (Mooney Tr.) at 27:10-20, 36:9 – 37:22 (noting from 2009 until 2012, she was a floater pharmacist and worked at 15-20 stores), 37:23 – 38:3 ("Q: Okay. When you were a floater from '09 to '12, what would you say the furthest was that you ever had to travel to go to a store to work? A: Forty-five minutes, maybe an hour."), 38:4-10, 40:10 – 41:9 (no information packets available to floaters to help orient them with the patient/physician base for that particular store), 59:13 – 60:10; Dkt. #3859-29 (Shaheen Tr.) at 114:23 – 115:2; **Ex. 20** (P-09555) at 00002; Dkt. #1968-5 (Mollica Tr.) at 15:17 – 16:2. *See also* Dkt. #3859-4 (6/15/21 Catizone Tr.) at 274:18 –

3. Giant Eagle failed to enforce, and monitor compliance with, its policies and procedures.

Even after developing its inadequate controlled substances diversion policies, Giant Eagle failed to monitor and enforce those policies across its pharmacies. In particular, despite recognizing the importance of performing due diligence for controlled substance prescriptions,[53] it failed to take adequate steps to ensure such due diligence was being performed.

Giant Eagle was certainly aware of the various red flags of diversion that must be investigated, despite not including such information in its controlled substance dispensing policies until mid-2013.[54] And Giant Eagle acknowledges that its pharmacists must resolve any red flags before filling an opioid prescription.[55] Yet in addition to failing to provide the tools necessary for their pharmacists to identify and resolve red flags (*supra* at § II.C.2),[56] Giant Eagle implemented

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275:1 ("Q: All right. So a pharmacist who is trying to evaluate how far the patient is from a pharmacy or the patient is from a prescriber has the address data from which he or she could figure that out? A: They may have the data, but if they are a pharmacist that's not familiar with the area and they are a floater in that system, the addresses may be meaningless to that pharmacist.") (internal objection omitted).

[53] **Ex. 14** (3/17/21 Tsipakis Dep. Ex. 2) at HBC_MDL00032658 ("We have a responsibility to our patients, professions and company to complete due diligence when filling prescriptions for controlled substances."); Dkt. #3859-6 (3/8/21 Chunderlik Tr.) at 39:6 – 40:22.

[54] *See, e.g.,* Dkt. #3859-30 (3/17/21 Tsipakis [GE 30(b)(6)] Tr.) at 10:3 – 11:12, 38:17 – 39:8, 41:9-17, 113:18 – 114:13 ("Q: And it's your testimony to this jury on behalf of Giant Eagle that these red flags are not new to Giant Eagle as of 2013, correct? A: Correct, nor are they exclusive."), 115:12 – 116:8; Dkt. #3859-31 (5/5/21 Tsipakis [GE 30(b)(6)] Tr.) at 210:13-20, 211:8-18, 213:2-9; **Ex. 14** (3/17/21 Tsipakis Dep. Ex. 2) at HBC_MDL00032663-2671; **Ex. 17** (3/17/21 Tsipakis Dep. Ex. 1) at HBC_MDL00191293-1294.

[55] Dkt. #3859-30 (3/17/21 Tsipakis [GE 30(b)(6)] Tr.) at 14:18-22 (pharmacists "need to assess the information that they have in front of them at the time of dispensing, and clear anything that they need to clear before they fill that prescription"), 16:19-23 ("If a pharmacist has a question about a prescription, it is incumbent on them to answer their questions that they have prior to filling a prescription in their judgment."); Dkt. #3859-31 (5/5/21 Tsipakis [GE 30(b)(6)] Tr.) at 44:7-11, 45:3-16.

[56] Giant Eagle also failed to adequately monitor whether its pharmacists were handling red flags correctly. The only report it ran with any regularity was the same "Threshold Report" utilized on the distribution side of the business. Dkt. #3859-30 (3/17/21 Tsipakis [GE 30(b)(6)] Tr.) at 73:11-15, 75:4-8, 78:4-16, 81:16-21, 82:4 – 83:1, 84:5-10, 88:14-21, 103:23 – 104:5 ("Q:…. What I'm asking you is, independent of those thresholds, is there any coding or any computer algorithm at Giant Eagle that would analyze physician prescriptions looking for patterns? A: Specific to the prescribers, no."); *see also* Dkt. #1968-5 (Mollica Tr.) at 48:11-17. And although Giant Eagle claims its corporate personnel were performing investigations regarding theft, loss, and other potential incidents of diversion, it dedicated only one or two employees to conduct these investigations across its 200+ pharmacies.

policies that hindered its pharmacists' ability to do so. For example, Giant Eagle: (i) denied their pharmacists the ability to institute blanket refusals to fill prescriptions from problematic prescribers;[57] (ii) failed to keep any logs of pain clinics or problematic prescribers for the use of its pharmacists to prevent diversion;[58] and (iii) instructed its pharmacists that the fact that a problematic prescriber was being investigated by the government for diversion or fraudulent practices was not a sufficient basis to refuse to fill a prescription.[59]

Additionally, Giant Eagle's employment metrics and financial incentives deterred its pharmacists from sufficiently exercising their corresponding responsibility duties. Giant Eagle admits that its pharmacists' "Annual Performance Reviews included goals to generally "Increase Profitability," "Increase Sales," and "Increase Script Volume," "(or some combination thereof"

Dkt. #3859-29 (Shaheen Tr.) at 96:12 – 97:5, 176:19 – 177:8, 284:21 – 285:7; **Ex. 21** (Shaheen Dep. Ex. 15).

[57] Dkt. #3859-21 (Mooney Tr.) at 294:11-15 ("I mean, there's nothing that's been put out that we don't fill a prescription for a particular provider. I've never – and I've never had that come from anyone at Giant Eagle."), 295:1-2 ("[W]e won't not fill a prescription for a prescriber."), 295:3-13, 296:9-14 ("Q:…. And what I thought I heard you tell me is that Giant Eagle doesn't have a blanket refusal-to-fill-type program where you don't refuse prescriptions from a particular providers? A: Right."), 297:5-13; Dkt. #1959-1 (Bencivengo Tr.) at 38:18-19 ("[W]e don't support just blankly saying we're not filling any prescriptions from a doctor."), 38:24-25 ("We don't have any list of doctors that we don't fill for.").

[58] Dkt. #1959-1 (Bencivengo Tr.) at 39:5-9 ("Q: Did you or anyone else at Giant Eagle keep a log or a record of bad doctors in Ohio that a prescription being written by them at least raised a red flag of concern? A: Again, no official log."), 40:24-25 ("We don't keep a list. There's no list of bad doctors."), 41:2-7 ("Q: Was there any report or log though or repository, anything where any information or data was kept about doctors or concerns about risk of diversion? A: Nothing on doctors, no") (internal objection omitted), 41:9-21 (same for pain clinics).

[59] **Ex. 22** (3/8/21 Chunderlik Dep. Ex. 5) (informing pharmacy team leader that she could continue filling prescriptions for pain management doctor being investigated by the DEA "for allegedly having workers forge prescriptions, falsifying patient records, and having inappropriate relations with a patient"); **Ex. 23** (3/8/21 Chunderlik Dep. Ex. 6) (when pharmacy team leader asked whether they should be filling prescriptions from pain clinic that only prescribed narcotics and in which one doctor was being charged with fraudulent billing and another had been shut off by an insurance provider, Giant Eagle responded that those circumstances were not "a blanket reason to not fill what they write"); Dkt. #3859-6 (3/8/21 Chunderlik Tr.) at 90:17 – 94:24, 100:2 – 102:21, 106:4 – 107:7; Dkt. #3859-31 (5/5/21 Tsipakis [GE 30(b)(6)] Tr.) at 65:23 – 66:9 ("[J]ust because they're being investigated . . . unless their prescribing powers or ability to prescribe medications either from the medical board or from the DEA are taken away, they are authorized to write prescriptions and to effectuate prescriptions."); Dkt. #1959-1 (Bencivengo Tr.) at 40:8-13.

and that "those goals were assessed based on profitability, sales, and script volume for the entire pharmacy at which the pharmacist worked[.]"[60] Moreover, Giant Eagle pressured its pharmacists to minimize the time it took to fill prescriptions.[61]

4. Giant Eagle pharmacies consistently filled red flag prescriptions without performing the necessary due diligence.

Based on Giant Eagle's dispensing data, Plaintiffs' experts identified hundreds of thousands of prescriptions containing one or more red flags[62] that were dispensed by Giant Eagle from 2006 to 2019 into the Counties.[63] The sheer number of red-flag prescriptions that were dispensed, along with the corresponding increase in opioid deaths in the Counties, indicates that many of these prescriptions were illegitimate and ultimately diverted.[64] Thus, Giant Eagle and its pharmacists either knowingly dispensed illegitimate prescriptions, or they failed to conduct the due diligence necessary to discover that the prescriptions were illegitimate.

Although Plaintiffs currently have some evidence demonstrating that Giant Eagle

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[60] **Ex. 24** (GE's Written Answer to 30(b)(6) Notice Excerpts) at pp. 10-11; **Ex. 25** (P-HBC-00037 Excerpts) at GE_TL00011879-1882, 1916, 1919; **Ex. 20** (P-09555) at 00002 (pharmacists' bonuses impacted by "Prescription Unit Volume," "Profitability," and "Customer Satisfaction"); **Ex. 26** (P-09545); **Ex. 27** (P-09546); **Ex. 28** (P- 09550); **Ex. 29** (P-09583); **Ex. 30** (P-14631); **Ex. 31** (P-14632); **Ex. 32** (P-14633); **Ex. 33** (P-14634).

[61] **Ex. 15** (Mooney Dep. Ex. 1 Excerpts) at HBC_MDL00190708 (noting "goal time" for filling prescription "is equal to 15 minutes for patients waiting and 90 minutes for patients returning later"), 0746; **Ex. 25** (P-HBC-00037 Excerpts) at GE_TL00011879-1882, 1895-1897 (time to fill a metric measured for performance evaluations).

[62] The red flags addressed in Mr. Catizone's report are ones that were known and understood to be red flags by Giant Eagle. *See, e.g.,* Dkt. #3852-3 (5/19/21 Catizone Supp. Rep.) at pp. 32-51 (patients traveling long distances to fill prescriptions; doctor shopping; pharmacy shopping; drug cocktails; excessive dispensing; pattern prescribing; early refills; excessive days of supply; payment in cash); **Ex. 14** (3/17/21 Tsipakis Dep. Ex. 2) at HBC_MDL00032665, 2667-2668, 2670-2671; **Ex. 17** (3/17/21 Tsipakis Dep. Ex. 1) at HBC_MDL00191293-1294.

[63] Dkt. #3852-12 (5/19/21 McCann Second Supp. Rep.) at pp. 3-4, 6, 10; **Ex. 34** (McCann Dep. Ex. 11 Excerpts); *see also* Dkt. #3852-10 (4/16/21 McCann Rep.) at pp. 119-120, 126-131, 150-156; Dkt. #3852-3 (5/19/21 Catizone Supp. Rep.) at pp. 32-51; Dkt. #3859-5 (6/16/21 Catizone Tr.) at 454:10 – 456:14.

[64] Dkt. #3859-4 (6/15/21 Catizone Tr.) at 174:3 – 176:25.

pharmacists were failing to conduct due diligence,[65] to date Giant Eagle has not completed production of its notes field information to Plaintiffs, which was ordered to be produced by the Court in May 2021. Dkt. #3726 (Amended Red Flag Order). As these notes fields (both electronic and on hardcopy prescriptions) are where Giant Eagle claims its pharmacists could document their due diligence,[66] this evidence is directly relevant to the question of whether Giant Eagle performed due diligence on red flag prescriptions. For these reasons, as explained in greater detail below, Plaintiffs are requesting that, to the extent the motion is not denied outright, any ruling on their dispensing-based claims be deferred until discovery is complete, pursuant to Federal Rule of Civil Procedure 56(d). *Infra* at § IV.C.

5. Giant Eagle's failures to implement effective controls against diversion when dispensing opioids resulted in diversion.

There are numerous documented instances of diversion (or potential diversion) resulting from Giant Eagle's failure to implement effective controls against diversion in its pharmacies in the Counties. *See, e.g.,* **Ex. 35** (Shaheen Dep. Ex. 11) (two GE pharmacies in Trumbull County (Pharmacies #1435 & #4002) filled several fraudulent prescriptions for opioids in 2014/2015); **Ex. 36** (Shaheen Dep. Ex. 8) (in 10/14, GE pharmacy in Trumbull County (Pharmacy #1405) lost 2,044 tablets of hydrocodone/APAP 10-325); **Ex. 37** (Shaheen Dep. Ex. 9) (one month later, same pharmacy (Pharmacy #1405) could not account for 465 tablets of hydrocodone/APAP 10-325); **Ex. 38** (Shaheen Dep. Ex. 10) (in 9/16, stolen prescription for controlled substance filled by GE pharmacy in Trumbull County (Pharmacy #4002)); **Ex. 39** (Shaheen Dep. Ex. 12) (in 5/17, GE pharmacy in Lake County (Pharmacy #6381) lost 120 tablets of hydrocodone/APAP 5/325 and 40

[65] *Supra* at fn.39. Moreover, there is evidence that Giant Eagle did not provide its pharmacists with the tools they would have needed to be able to conduct adequate due diligence. *Supra* at § II.C.2.

[66] *See, e.g.,* Dkt. #3859-30 (3/17/21 Tsipakis [GE 30(b)(6)] Tr.) at 144:2-21.

tablets of amphetamine 15 mg); **Ex. 21** (Shaheen Dep. Ex. 15) (in 2018, pharmacy technician admitted to stealing over $6,000 worth of controlled substances from pharmacy in Lake County (Pharmacy #6377) and in another pharmacy in Trumbull County (Pharmacy #4051), one pharmacy technician stole product, another stole money, and a third was selling meth out of the pharmacy; also notes that "[o]ur newest case involves 2 nurses that falsified over 200 prescriptions causing thousands of Hydrocodone a CII to be dispense [sic] illegally"); **Ex. 40** (Shaheen Dep. Ex. 17) (8/18 pharmacy hot sheet for GE pharmacy in Trumbull County (Pharmacy #4002) states fraudulent script for oxycodone "passed at 2 of our pharmacies in Ohio").[67]

These incidents are consistent with Giant Eagle's failures to implement effective controls against diversion in its other pharmacies throughout Ohio,[68] including some in nearby counties. *See, e.g.,* **Ex. 21** (Shaheen Dep. Ex. 15); **Ex. 43** (Shaheen Dep. Ex. 18 Excerpts) at OBPM_MDL_000000031.0011-0017 (in proceeding against GE pharmacist at Stark County store (Pharmacy #4152), Ohio BOP found that, between 4/30/06 and 5/20/09, pharmacist, *inter alia*, "failed to provide supervision and control and adequate safeguards over the listed Giant Eagle #4152 dangerous drug stocks, to wit: [various] dangerous drugs were diverted without detection[,]" including opioids and other cocktail drugs); **Ex. 44** (Shaheen Dep. Ex. 19 Excerpts) at OBPM_MDL_000000063.0003-0006 (GE entered into 2011 settlement agreement with Ohio BOP to resolve allegations that its Chardon, Ohio store in Geauga County (Pharmacy #4098) "did,

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[67] *See also* **Ex. 38** (Shaheen Dep. Ex. 10) (in 6/15, bottle of morphine IR 30-mg improperly disposed of at GE pharmacy in Trumbull County (Pharmacy #4002)); **Ex. 41** (Shaheen Dep. Ex. 13) (in 12/17, GE pharmacy in Trumbull County (Pharmacy #4056) mistakenly dispensed 120 tablets of norco 10 instead of 90); **Ex. 42** (Shaheen Dep. Ex. 14) (same); Dkt. #3859-29 (Shaheen Tr.) at 217:3 – 218:3, 219:1 – 221:11, 225:6 – 227:24, 230:7 – 237:19, 239:14 – 240:21, 243:8 – 244:3, 248:13 – 250:23, 251:17-24, 254:17 – 257:5, 259:7-11, 269:14 – 272:6, 273:16 – 277:22, 282:1 – 283:11, 284:1 – 285:7, 287:2 – 290:4, 297:2 – 298:5, 373:16 – 376:5, 377:17 – 379:12.

[68] Every Giant Eagle pharmacy implements the same dispensing policies. Dkt. #3859-29 (Shaheen Tr.) at 363:4-24, 364:19 – 365:1.

from May 1, 2009, through January 21, 2011, fail to provide effective and approved controls and procedures to deter and detect theft and diversion of dangerous drugs" resulting in the theft and diversion of opioids); **Ex. 45** (Shaheen Dep. Ex. 20 Excerpts) at OBPM_MDL000000184.0015-0018 (GE entered into 2017 settlement agreement with Ohio BOP to resolve allegations that its Columbus, Ohio store in Franklin County (Pharmacy #6501) "fail[ed] to report significant drug losses to the Board"; "[T]he Board has evidence sufficient to sustain the allegations, finds them to violate Ohio's pharmacy law as set forth in the Notice, and hereby adjudicates the same."); **Ex. 46** (Shaheen Dep. Ex. 21) (internal 7/19 GE email stating: "A drug ring involving multiple individuals were arrested in our parking lot for selling their Percocet. *They would purchase the medication at our pharmacy* and the [sic] meet up with others to sell their pills.") (emphasis added).[69]

III. LEGAL STANDARD

Pursuant to FED. R. CIV. P. 56(c), the moving party has the burden of showing that no genuine dispute exists as to any material fact. *See Hickle v. Am. Multi-Cinema, Inc.*, 927 F.3d 945, 951 (6th Cir. 2019). The defendant also has the burden of proof on all affirmative defenses. *See Fonseca v. Consol. Rail Corp.*, 246 F.3d 585, 590 (6th Cir. 2001) (internal citations omitted). Summary judgment must be denied "if a reasonable jury could return a verdict for the nonmoving party[.]" *Kolesar v. Allstate Ins. Co.*, 2019 WL 2996047, at *2 (N.D. Ohio July 9, 2019) (Polster, J.) (citing *Baynes v. Cleland*, 799F.3d 600, 606 (6th Cir. 2015)). In making this determination, the Court "must view the facts and any inferences reasonably drawn from them in the light most favorable to the nonmoving party." *Id.* (citing same). Courts do not weigh the

[69] *See also* Dkt. #3859-29 (Shaheen Tr.) at 309:11 – 310:1, 312:3 – 314:8, 316:10 – 327:3, 334:10 – 343:4, 346:11 – 348:14, 351:7 – 358:12, 369:8 – 371:4.

evidence or otherwise engage in "jury functions" in deciding a motion for summary judgment; "[i]f there remains any material factual disagreement as to a particular legal claim, that claim must be submitted to a jury." *Hickle*, 927 F.3d at 951 (citing *Bobo v. United Parcel Serv., Inc.*, 665 F.3d 741, 748 (6th Cir. 2012)).

Additionally, if a nonmovant is able to show "by affidavit or declaration that, for specified reasons, it cannot present facts essential to justify its opposition," the Court can:

(1) defer considering the motion or deny it;

(2) allow time to obtain affidavits or declarations or to take discovery; or

(3) issue any other appropriate order.

FED. R. CIV. P. 56(d). The purpose of this rule "is to ensure that plaintiffs receive a full opportunity to conduct discovery to be able to successfully defeat a motion for summary judgment." *Doe v. City of Memphis*, 928 F.3d 481, 490 (6th Cir. 2019) (citations and internal quotation marks omitted).

When determining the appropriateness of a Rule 56(d) request, courts consider five factors: (1) when the party "learned of the issue that is the subject of the desired discovery;" (2) whether the desired discovery would change the summary judgment ruling; (3) "how long the discovery period had lasted;" (4) whether the party "was dilatory in its discovery efforts; and (5) whether the opposing party "was responsive to discovery requests." *Id*. at 491 (citation and internal quotation marks omitted). Although the Sixth Circuit reviews a district court's Rule 56(d) determination under an abuse of discretion standard, it has emphasized that motions "'requesting time for additional discovery should be granted almost as a matter of course unless the non-moving party has not diligently pursued discovery of the evidence.'" *Id*. at 490-91 (citation omitted).

IV. ARGUMENT

A. THE GE DEFENDANTS ARE NOT ENTITLED TO "SAFE HARBOR" IMMUNITY.

The GE Defendants argue they are entitled to "safe harbor" immunity because various DEA and Ohio Board of Pharmacy ("Ohio BOP") investigations and audits demonstrate that Giant Eagle complied with its regulatory obligations. Ds' MOL, pp. 17-25. This argument is entirely without merit. The GE Defendants bear the burden of proving their entitlement to this affirmative defense. *See Fonseca*, 246 F.3d at 590; *Leach v. Elec. Rsch. & Mfg. Coop., Inc.*, No. 15-1221, 2016 WL 6892797, at *4 (W.D. Tenn. Nov. 22, 2016) ("The defendant's burden to prove an affirmative defense is a heavy one and is difficult to carry at the summary judgment stage."). They have failed to do so. To the contrary, the record evidence clearly demonstrates triable issues of fact as to the GE Defendants' compliance with the statutory and regulatory obligations applicable to their distribution and dispensing of opioids. Summary judgment on this ground should be denied.

1. "Safe harbor" immunity applies only when the defendant has performed in accordance with its regulatory obligations.

As this Court has repeatedly stated, "under Ohio law, ''safe harbor' immunity from absolute nuisance liability is available *only* to those who perform in accordance with their applicable licensing regulatory obligations.'" Dkt. #3403 (CT3 MTD Order) at pp. 29-30 (quoting Dkt. #3177 (Cleveland Bakers MTD Order) at pp. 45-47 (emphasis added). The authority cited by the GE Defendants supports this position.[70]

[70] *See City of Cleveland v. Ameriquest Mortg. Sec., Inc.*, 621 F. Supp. 2d 513, 516, 526, 531 (N.D. Ohio 2009) (dismissing public nuisance claim based on "epidemic of foreclosures" allegedly caused by subprime lending where plaintiff "does not claim that the underlying subprime mortgage lending was illegal" or that defendants "violated any of the myriad laws governing mortgage lending"; "[C]onduct which is *fully authorized* by statute or administrative regulation is not an actionable tort.") (emphasis added); *Hager v. Waste Technologies Industries*, No. 2000-CO-45, 2002 WL 1483913, at *10-11 (Ohio App. 7 Dist. June 27, 2002) (defendant's "*mere existence or operation*" of waste incineration facility did not qualify as a common law public nuisance, where facility was licensed to operate its plant and it operated under sanction of law; "[C]onduct, which is fully authorized by statute or administrative regulation, is not actionable as a public nuisance.") (emphasis in original); RESTATEMENT

The legal obligations on distributors and dispensers of opioids under the CSA have been clearly delineated by this Court in prior rulings. To begin with, *all* registrants must "provide effective controls and procedures to guard against [i] theft *and* [ii] diversion of controlled substances.'" Dkt. #3403 (CT3 MTD Order) at p. 15 (emphasis in original) (quoting 21 C.F.R. § 1301.71(a)). With regard to opioid distributors, the Court has explained that they are required to: (1) "design and operate a system to disclose to the registrant suspicious orders;" (2) "inform the DEA of suspicious orders when discovered by the registrant[;]" and (3) not "ship suspicious orders" "unless due diligence reasonably dispels the suspicion." Dkt. #2483 (CT1 CSA MSJ Order) at pp. 15, 18-19.[71]

Regarding dispensers of opioids, the Court has explained that: (1) both the individual pharmacists *and* the pharmacy registrant bear the responsibility to guard against invalid prescriptions[;] (2) dispensers of controlled substances must "check for and conclusively resolve red flags of possible diversion prior to dispensing those substances[;]" (3) pharmacies must collect and retain specific data-points that would inarguably be useful to the pharmacy (or the DEA) in identifying suspicious prescribing and dispensing activity" in order to "guard against diversion[;]" and (4) "a pharmacy may not fill a prescription that it knows or has reason to know is invalid and may not remain deliberately ignorant or willfully blind of the prescription information it has

(SECOND) OF TORTS § 821B cmt. f ("Although it would be a nuisance at common law, conduct that is *fully authorized* by statute, ordinance or administrative regulation does not subject the actor to tort liability.") (emphasis added).

[71] The Court has also recognized that determinations regarding the adequacy of a distributor's SOM system raises a multitude of fact issues. *See, e.g., id*. at p. 21 (noting "there are disputes of fact as to whether, and when, each Defendant's SOMS was adequate, whether orders were suspicious, and whether each Defendant did actually ship suspicious orders (or instead, identified it as suspicious but then, through due diligence, dispelled that suspicion"); Dkt. #3101 (CT1 HBC MSJ Order) at p. 4 (finding "triable issue of fact regarding the adequacy of HBC's suspicious order monitoring system").

(including computerized reports it generates)." Dkt. #3403 (CT3 MTD Order) at pp. 14-22, 25; Dkt. #3499 (CT3 Reconsideration Order) at p. 7.

In this case, as set forth below, the evidence demonstrates that the GE Defendants failed to perform in accordance with their obligations under the CSA and its implementing regulations. *Infra* at § IV.A.3-5. Accordingly, the GE Defendants are not entitled to "safe harbor" immunity.

2. The investigations conducted by the DEA and the Ohio BOP do not establish that the GE Defendants' distribution and dispensing activities complied with applicable law.

The GE Defendants claim that the various DEA and Ohio BOP inspections of their distribution facilities and pharmacies establish as a matter of law that the GE Defendants complied with their statutory and regulatory obligations because those agencies found no violations and determined the GE Defendants were acting lawfully. Not so.

i. The DEA never approved or endorsed HBC/GERX's SOM systems, nor did it analyze or investigate whether the implementation of such systems complied with applicable law.

That various pre-registration and cyclic investigations of the HBC and GERX facilities by the DEA resulted in no findings of violations or administrative actions cannot be considered an official determination by that agency that the GE Defendants' distribution conduct, or its SOM systems, complied with applicable regulations. As a preliminary matter, it is well established that the DEA does not approve or endorse any distributor's specific SOM system.[72] The DEA has been

[72] **Ex. 47** (12/13/18 Tsipakis Dep. Ex. 13) at ABDCMDL00269683, 9685; Dkt. #3859-7 (Colosimo Tr.) at 137:1-17 ("Q: And, sir, is that consistent with your understanding and your training with the DEA that certain SOM policies, procedures, including due diligence, were not sanctioned or approved by the DEA? A: That's my understanding, yes."), 139:23 – 140:10, 189:16 – 190:6 ("Q:…. Mr. Colosimo, you would agree that under no state, form or fashion did the DEA approve or otherwise endorse any specific system for reporting suspicious orders, correct, sir? A: That is what is indicated in the letter from Rannazzisi and, from my experience, I did not approve or endorse the suspicious order system. Q: And that is also consistent with your training at the DEA, that investigators did not approve suspicious order systems, correct, sir? A: Yes.") (internal objection omitted).

clear on that since well before the GE Defendants began distributing opioids.[73] It is therefore incumbent upon the registrant to design and implement a SOM system that complies with the applicable regulations.[74]

Contrary to the GE Defendants' assertions,[75] the DEA inspections at issue were quite limited in scope. The investigators were simply looking at whether the GE Defendants *had* a SOM system.[76] They did not analyze whether that system was being *implemented* in accordance with the CSA and its regulations. Dkt. #3859-7 (Colosimo Tr.) at 109:10-11 ("I did not evaluate the system. I described the system."), 188:1-2 ("I don't know how effective Giant Eagle's system was.");[77] Dkt. #3859-3 (11/13/20 Brennan [DEA 30(b)(6)] Tr.) at 33:7-17 ("Q: What if there was a system in place but the investigator didn't think it was good enough; the investigator would tell the distributor that, right? A: No. The investigator is trained to – to ensure that there is a system in place as required by the regulations. The investigator's also trained not to approve nor disapprove the system.") (internal objection omitted).[78] They were not reviewing the thousands

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[73] **Ex. 47** (12/13/18 Tsipakis Dep. Ex. 13) at ABDCMDL00269685; Dkt. #3859-7 (Colosimo Tr.) at 137:1-17.

[74] Dkt. #3859-3 (11/13/20 Brennan [DEA 30(b)(6)] Tr.) at 34:2-7 ("Only the registrant knows their customers, and they're the ones that are required to know whether their system is sufficient to detect suspicious orders."); Dkt. #3859-7 (Colosimo Tr.) at 137:18 – 138:4, 139:17-22; Dkt. #3027-32 (12/13/18 Tsipakis [HBC 30(b)(6)] Tr.) at 104:3-5, 127:22 – 128:7, 298:12 – 299:22.

[75] The GE Defendants cherry-pick the testimony of DEA Diversion Investigator Lewis Colosimo throughout their motion to support their position, but as discussed herein, his testimony in fact refutes their arguments.

[76] Dkt. #3859-3 (11/13/20 Brennan [DEA 30(b)(6)] Tr.) at 30:19 – 31:1, 32:18-22, 32:24 – 33:5, 203:2-12; Dkt. #3859-7 (Colosimo Tr.) at 108:20-21, 109:10-18, 191:22-23 ("What I do is ensure that they have a system.").

[77] *See also id.* at 108:20-24 ("In my report I described the system as represented to me by Giant Eagle. *I did not evaluate its effectiveness*. I just – I completely described it as they represented to me in – with the handout that they gave me.") (emphasis added), 169:14 – 170:2 ("Q: Sir, did it remain consistent with your practice at the DEA and Exhibit 8, this report of investigation, that the DEA was not approving HBC/Giant Eagle's SOM policies and/or systems that were in place, correct? A: We reviewed the policy to the extent that it was summarized in the description of what they were doing, *but we did not sanction* – me personally and my supervisor, Mr. Dittmer, *did not sanction or approve of that suspicious order system in place*.") (internal objection omitted) (emphasis added), 187:15 – 188:1.

[78] *See also id.* at 118:5-13, 133:22 – 134:8 (investigators trained to "just ask about . . . the system that's in place

of suspicious (or potentially suspicious) orders or the GE Defendants' handling of same, nor would it have been feasible for them to do so.[79] Indeed, Giant Eagle's Senior Manager of Pharmacy Compliance acknowledged as much:

> Q: Are you aware of any time that the DEA conducted an investigation specifically to determine whether or not HBC was in compliance of the monitoring requirements of the Controlled Substances Act?
>
> A: *It never came up in any of the inspections that I know of.*

Dkt. #1959-24 (1/16/19 Chunderlik Tr.) at 294:2-8 (emphasis added).

Moreover, the DEA investigators were relying on limited information given to them by the GE Defendants and assuming that what was provided to them was both complete and accurate.[80]

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and record what the company tells them that they have one in place"); Dkt. #1969-21 (5/15/19 Rannazzisi Tr.) at 569:24 – 570:17 ("Q: And [the diversion investigators] would have taken a look at [SOM] systems in many cases, correct? A: I would say they would do a cursory review. You – you can't look at a [SOM] system unless . . . you're actually watching it work. And to watch it work, you have to execute. And to execute, you have to follow your protocols and procedures. So you might have a great [SOM] system. But if you're not . . . actually executing what's in your protocols and procedures, the system is worthless."), 570:18 – 571:3.

[79] Dkt. #3859-7 (Colosimo Tr.) at 167:12 – 169:1 ("Q: From orders from the pharmacies to – HBC/Giant Eagle pharmacies to – for oxy and hydro. You were not reviewing those orders one by one, correct, sir? A: One by one, we did not do that, I did not do that. Q: Yes, sir. And part of your investigations – you weren't reviewing these millions of pills and the orders during your investigations, correct, sir? A: My investigation was the pre-registrant investigation of HBC, then later the Giant Eagle facility. Q: In the course of those investigations or your reviews, it was not the DEA's practice to review order by order, correct, sir? A: It was – that was not my practice, and I don't – I can't speak to the other investigators, but my experience is that we would not have been reviewing order by order. Q: And sir, it would almost be – based on your practice and experience, it would be impossible to review the hundreds of thousands or millions of orders that came in through HBC's pharmacies during the scope of your investigation, correct? A: You had mentioned or asked a few times order by order. That's not something that – that I would have been doing for my investigations, order by order. Q: Or that you observed any other DEA investigators reviewing orders, correct, sir? A: Correct. I did not observe other investigators reviewing order by order.") (internal objections omitted); Dkt. #3859-3 (11/13/20 Brennan [DEA 30(b)(6)] Tr.) at 168:3-11 ("Q: And at no point during the audit would the DEA's DIs, diversion investigators, would they ever review these tens of thousands of pages of suspicious orders and analyze those from a statistical perspective, correct? A: No, there was no requirement by DEA for DIs to do that.") (internal objection omitted).

[80] Dkt. #3859-3 (11/13/20 Brennan [DEA 30(b)(6)] Tr.) at 134:4-8, 172:13-19 ("Q:… The DEA, when performing its audit, relies heavily on the information given to it by the registrant, correct? A: Yes.") (internal objection omitted), 172:21 – 173:6, 185:7 – 188:25; Dkt. #1969-14 (5/17/19 Prevoznik [DEA 30(b)(6)] Tr.) at 947:7 – 948:4 ("Q: Okay. And you, the DEA, can't always see what distributors don't do or do wrong, especially if they're trying not to be caught, correct? A: Correct.") (internal objections omitted); Dkt. #3859-7 (Colosimo Tr.) at 96:8-16 ("Q: So can't we conclude that your understanding was that everything that Giant Eagle proposed to do at its HBC facility was going to be in compliance with the security requirements? A: What they proposed to do, *what they assured me, assured DEA that they were going to do* would be in compliance, and *based on that*,

And as the DEA explained, the fact that no violations are found or no formal actions are taken against a registrant does not establish that it was in compliance with its obligations.[81]

ii. The Ohio BOP inspections were not official determinations that Giant Eagle's dispensing conduct complied with applicable law.

The same is true for the Ohio BOP inspections cited by the GE Defendants. Those inspections were also extremely limited in scope.[82] The inspector's findings were based only on what he or she was able to observe during the few hours of the inspection and the limited information provided by the pharmacist in response to the inspector's questions.[83] The inspector

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the application was approved.") (emphasis added), 108:20-24, 109:11-18; **Ex. 48** (Shaheen Dep. Ex. 4); Dkt. #3859-29 (Shaheen Tr.) at 128:4-22 (told DEA that warehouse had no hydrocodone-containing products on hand when in fact they had one case of hydrocodone); Dkt. #3859-27 (6/10/21 Rafalski Tr.) at 213:13-23, 214:10 – 215:9, 216:1-23; Dkt. #3859-28 (6/11/21 Rafalski Tr.) at 461:17 – 462:4.

[81] Dkt. #1969-14 (5/17/19 Prevoznik [DEA 30(b)(6)] Tr.) at 946:3 – 947:5 ("Q:… And the fact that DEA doesn't alert a registrant to a problem with their [SOM] program doesn't mean the problem doesn't exist, does it? A: Yes.") (internal objections omitted), 947:7 – 948:4. *See also* Dkt. #3859-7 (Colosimo Tr.) at 93:24 – 94:4; Dkt. #3859-28 (6/11/21 Rafalski Tr.) at 455:4-17 (noting he "didn't put a high value on [prior DEA inspections of Giant Eagle] because in my experience with the cases I have worked, generally there would be clean inspections during the time frame where I took action, in regarding specifically, Masters and Mallinckrodt."), 487:14 – 488:4 ("Q: Okay. And then they say, 'Investigator Conlon advised Rogos to develop a better system of due diligence.' Do you see that recommendation that he made to Giant Eagle? A: I do. Which kind of contradicts the earlier statement. . . . I don't know that a registrant could be in full compliance and at the same time get a corrective statement like that in the report."), 494:24 – 495:1 ("I think the last DEA-6 we reviewed together would show they were not in full compliance."), 495:4-12 ("The reports say that they needed to do a better job at doing their due diligence. They did come to the conclusion that it was in compliance, but I believe contained within the report it kind of is contradicted by some of the statements.").

[82] Dkt. #3859-8 (DiFrangia Tr.) at 193:22 – 194:18 ("Q: And have you, Agent DiFrangia, ever analyzed a retail pharmacy chain's data, dispensing data, to see how much information that data has that might identify some of these data anomalies? A: I mean, I have reviewed data for retail pharmacies, but I don't know that I've necessarily reviewed it for data anomalies. You know, I've reviewed it for trying to find a certain prescription or something of that nature, but as far as I recall, I don't know that I've ever reviewed a retail chain pharmacy. I've done retail independent pharmacies but not a retail chain pharmacy. Q: So when you testified earlier that with respect to your 2018 full inspection of the Giant Eagle pharmacy, that you looked at and approved their dispensing data system, that was done on a very limited basis, correct? A: Yes. It is a – it's a limited basis.") (internal objection omitted); Dkt. #3859-22 (Pavlich Tr.) at 266:11-25.

[83] Dkt. #3859-8 (DiFrangia Tr.) at 174:16-20 ("Q: And when you do an inspection once a year, that's really a snapshot of a couple of hours of experience with a pharmacy at that particular time, correct? A: That's correct."), 175:1-14 ("Q: So when you do a full inspection, like you did in 2018, that's just really a couple-hour snapshot in time, correct? A: Yes."), 197:12-22, 207:18 – 208:4, 210:8-13 ("Q: Okay. So when you, for example, made the conclusion that there was adequate staffing, that was based upon your observations during this time frame at the Giant Eagle store, right? A: Yes."), 210:14-21, 213:9-21 ("Q: And the second question under Record Availability

would often look at only a few prescriptions and/or one patient profile during the inspection.[84]

Significantly, the Ohio BOP inspectors *did not* review Giant Eagle's corporate policies related to dispensing, nor the implementation of such policies. *See, e.g.,* Dkt. #3859-8 (DiFrangia Tr.) at 203:9-20 ("Q: Well, certainly your inspection and that of the other agents doesn't look at that question, does it? . . . . The question of whether or not the retail pharmacy chain that employs these pharmacists is giving the pharmacist adequate information from their dispensing data to help that pharmacist carry out his corresponding responsibility. A: I mean, that specific question is not asked during an inspection."); Dkt. #3859-9 (Edwards Tr.) at 168:23 – 169:8 ("Q: There's a reference to the DUR verification system on page 1. Does that reflect that part of this inspection, you reviewed the adequacy of the record system, including DUR verification? A: That tells me that their system was capable of doing those things. *I don't know that I specifically went in and checked prescriptions to make sure there was DUR done*, but it's telling me that that software is capable of doing those things.") (emphasis added); Dkt. #3859-22 (Pavlich Tr.) at 264:25 – 265:4

says, 'Can the pharmacy produce three years of dispensing records within three days?' And the answer was 'Yes.' How did you get that information? A: From what I recall, I probably just asked for it. Q: Okay. So you didn't – you didn't ask anybody to go into the records or into the data on the computer system to confirm that they could do that, correct? A: No. I just asked them if they were able to produce records within three days."), 214:3-24 (in determining whether pharmacy has "a real time online system used for review and transfer of dispensing data[,]" inspector would not look at data himself, but rather "would ask the pharmacist" and rely on his or her answer), 215:21 – 216:17; Dkt. #3859-22 (Pavlich Tr.) at 264:15-18; Dkt. #3859-9 (Edwards Tr.) at 183:5-15 ("Q:…. Is that something that you evaluated at the stores when you did your inspections, were they adequately staffed with respect to pharmacists and techs and employees? A: That's generally a question that we would ask the pharmacist or . . . or if we observe, you know, something like the place is totally chaotic and things are out of control, then, I mean, it would be based on firsthand observation.").

[84] Dkt. #3859-8 (DiFrangia Tr.) at 195:19-22 ("Q: But what you actually did is you looked at one patient, one patient's profile, correct? A: Yes."), 196:18-21, 197:12-22 ("Q:… But in terms of actually looking at what a particular pharmacist working for Giant Eagle pharmacy actually did or does, you were looking at, first of all, one snapshot in time, and in terms of the patient profile, one patient profile, correct? A: Yes, it's a snapshot in time.") (internal objection omitted), 212:14-20, 215:1-7; Dkt. #3859-9 (Edwards Tr.) at 175:18-25 ("Q: And then you mention on page 3, controlled substance II files checked, prescriptions properly contain prescriber, DEA, quantity, et cetera. So Giant Eagle was meeting the prescription information requirement; is that right? A: *On the prescriptions I checked*, yes.") (emphasis added).

("Q: You never investigated what data was available to pharmacists that had been accumulated at the corporate level from all this dispensing data, correct? A: No, I never investigated that."), 272:2-8 ("Q: Right. Have you done any investigation of any of the retail pharmacies regarding what written policies they have that governs the conduct of their pharmacists who dispense opioids? A: I would say no."), 272:13-24 ("A: No, I had no knowledge of their internal memos or documents. None that I recall. Q: And your investigations never revealed any of those policies to you, did they? A: No. I would say it had not.").[85]

And even with the limited nature of these investigations, some investigations did uncover violations.[86] Moreover, not all of an inspector's concerns were necessarily documented in the

[85] *See also id.* at 262:3-10 ("Q: So between 1987 and 2006, when this OARRS system came online in the state of Ohio, did you ever, in the course of your investigation, ask any of the pharmacies that you investigated what data they had available to them or that was stored by their corporate offices? A: Never asked that question, no."), 265:5 – 266:25, 272:25 – 273:12 ("A: My inspections would show what software they had in the pharmacy. Beyond that extent, I just documented what software they had. I – I'm computer dumb. Q: But what information in terms of data analysis that software provided, you would have no idea, correct? A: Yeah, correct."); Dkt. #3859-8 (DiFrangia Tr.) at 190:18 – 191:6 ("Q: In the course of your interaction with any of the retail pharmacies during you annual inspections, have you ever inquired of any of the pharmacists whether they are provided with corporate analysis of dispensing data? A: No, I don't know that I've ever asked that during an inspection. Q: Have you ever asked them whether they receive reports from their corporate offices on how to use – or policies on how to use dispensing data to analyze the data anomalies and red flags that are listed on Exhibit 9? A: I have never asked that of them."), 216:2-6 ("Q:…. [D]id you ask for the data on the number of opioid prescriptions that were filled during any particular time frame at that store? A: No."), 217:24 – 218:5 ("Q: Have you ever inquired of the retail chain pharmacies whether or not they have a bonus system or ever had a bonus system for their pharmacist that was driven by the number of prescriptions that they filled either per hour or per day? A: No, I have not."); Dkt. #3859-9 (Edwards Tr.) at 175:4-17 (when asked about reference to DUR verification process in inspection report, he explained it was him "documenting that the pharmacy had that system, which was capable of doing those things").

[86] Dkt. #3859-9 (Edwards Tr.) at 187:6 – 189:12 (discussing inspection in which he requested follow-up regarding an improper dispensing, DUR software, OARRS, and records; "I believe that pharmacist was either not even signed up for OARRS or never ran OARRS reports. So that was – that was kind of a big deal. I don't know – I don't know that I was satisfied. I seem to recall possibly there was maybe a hearing involving this pharmacist or – I don't recall specifically, but I think there might have been additional action taken against this pharmacist."); Ds' SJ-Ex. 11 at pp. 72 (regarding one controlled substance prescription: "The pharmacist received a DUR warning for therapeutic duplication and completed a DUR overrise without taking any documented steps to resolve the issue. Neither of the prescribers were called, an OARRS report was not run and there is no documentation that the patient was counseled about taking an increased dose of the medication."), 240, 436 (failed to report drug loss to Ohio BOP immediately upon discovery), 716.

short reports.[87] Additionally, two of the Ohio BOP inspectors who inspected Giant Eagle's pharmacies in the Counties admitted they were not knowledgeable enough to make any determinations as to whether Giant Eagle and its pharmacists were identifying and resolving red flag prescriptions in accordance with their CSA obligations, or whether Giant Eagle was providing its pharmacists the sufficient tools to do so. Dkt. #3859-8 (DiFrangia Tr.) at 191:7-16 (admitting he did not know whether dispensing data would be a helpful tool to pharmacists in carrying out their corresponding responsibility; "You know, I don't know if that would be helpful because I'm not a pharmacist.");[88] Dkt. #3859-22 (Pavlich Tr.) at 229:4-6 ("Q: In the context of dispensing, what does – what does a red flag mean? A: I have no idea. I never used it."), 255:4-10 ("Q: Are you aware of the fact, Agent Pavlich, that the Controlled Substances Act imposes obligations on distributors and pharmacies to develop systems that prevent diversion? A: No. Beyond my scope. Beyond my classification of what I did. I don't know.").

The fact that Giant Eagle was acting unlawfully (*i.e.*, failing to implement effective controls against diversion) in spite of these purportedly "clean" Ohio BOP inspections is evidenced by the fact that there are documented instances of diversion in the very same pharmacies that were inspected by the Ohio BOP. *Supra* at § II.C.5. For example, there is evidence that certain Giant Eagle pharmacies in the Counties filled fraudulent/stolen opioids prescriptions (Pharmacies #1435 & #4002), lost or improperly disposed of opioid prescriptions (Pharmacies #1405, #4002, &

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[87] Dkt. #3859-22 (Pavlich Tr.) at 166:10 – 169:1 (Agent Pavlich would sometimes see evidence of insufficient staffing in pharmacies, but he would not necessarily note that in his report).

[88] *See also id.* at 191:18 – 192:4, 201:18 – 202:3 ("Q:…. Now, can we agree that when a pharmacist is exercising his judgment in fulfilling this corresponding responsibility, the pharmacy that he works for has the obligation of giving the pharmacist adequate tools to be able to do his job, correct? A: I don't know.") (internal objection omitted), 202:4-14 ("Q: Well, with respect to information coming from dispensing data that the pharmacist might want to utilize to exercise his corresponding responsibility, the information is only as good as that which is provided to the pharmacist by his employer, the pharmacy, correct? A: I don't – I don't know what a pharmacist would want or need because I am not a pharmacist.") (internal objection omitted), 224:9-25.

#6381), dispensed incorrect amounts of opioids (Pharmacy #4056), and had employees stealing and selling drugs out of the store (Pharmacies #6377 & #4051). *Id*. Yet the Ohio BOP inspected each of these pharmacies on numerous occasions. Ds' SJ-Ex. 11 at pp. 267-328, 339-346, 383-405 (Pharmacy #1405), 496-510 (Pharmacy #1435), 512-532 (Pharmacy #4002), 534-556 (Pharmacy #4051), 558-596 (Pharmacy #4056), 604-695 (Pharmacy #6377), 696-736 (Pharmacy #6381).

iii. The GE Defendants could not have reasonably relied on DEA or Ohio BOP investigations, or such agencies' failure to sanction or institute administrative actions against the GE Defendants, as official agency determinations that their distribution and dispensing of opioids complied with all applicable regulations.

As a preliminary matter, a determination of reasonable reliance is a fact question not appropriately resolved on summary judgment. *See Bass v. Janney Montgomery Scott, Inc.*, 210 F.3d 577, 590 (6th Cir. 2000) ("[T]he question of whether [a party's] reliance was reasonable is beyond doubt a question of fact for a jury to decide, and not a fit subject for judgment as a matter of law."). In this case, there is ample evidence demonstrating that the GE Defendants did not reasonably rely, nor could they have reasonably relied, on any DEA or Ohio BOP investigations or inaction as affirmations of the lawfulness of its conduct.

The GE Defendants' duties under the CSA and its implementing regulations are clear.[89]

[89] In addition to the plain language of the statute and implementing regulations, the DEA has published on the Federal Register numerous decisions, opinions, and administrative actions that describe the obligations of distributors and dispensers under the CSA at length. *See, e.g., Southwood Pharmaceuticals, Inc.; Revocation of Registration*, 72 FR 36487-01, 36498-500, 2007 WL 1886484 (D.E.A. July 3, 2007); *East Main Street Pharmacy*; *Affirmance of Suspension Order*, 75 FR 66149-01, 66163, 2010 WL 4218766 (D.E.A. Oct. 27, 2010); *Holiday CVS, L.L.C., d/b/a CVS/Pharmacy Nos. 219 and 5195 Decision and Order*, 77 FR 62316-01, 62341, 2012 WL 4832770 (D.E.A. Oct. 12, 2012). This information is "routinely review[ed]" by registrants. Dkt. #3859-28 (6/11/21 Rafalski Tr.) at 514:1-10; *see also* Dkt. #3859-2 (Ashley Tr.) at 115:14-19, 116:7-21, 117:14-21; Dkt. #3859-7 (Colosimo Tr.) at 145:16 – 146:9; **Ex. 47** (12/13/18 Tsipakis Dep. Ex. 13) at ABDCMDL00269684; Dkt. #1969-21 (5/15/19 Rannazzisi Tr.) at 567:14-18.

They have not changed during the relevant time period.[90] As registrants, the GE Defendants were obligated to familiarize themselves with these legal requirements.[91] And, in fact, the evidence demonstrates that the GE Defendants did know and understand their legal obligations regarding the distribution and dispensing of controlled substances during the relevant time periods.[92]

Given their knowledge and understanding of the relevant law, along with the extensive evidence of their unlawful conduct (*infra* at § IV.A.3-5), a jury could reasonably conclude that the GE Defendants knew or should have known that their distribution and dispensing conduct did not comply with their legal obligations. The GE Defendants were also aware of the limited nature of the DEA and Ohio BOP inspections and, particularly, that the inspectors were not analyzing the implementation of their SOM systems or dispensing policies and procedures. *Supra* at § IV.A.2.i-ii.[93] Certainly the GE Defendants have offered no evidence that any DEA or Ohio BOP inspector

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[90] Dkt. #3859-3 (11/13/20 Brennan [DEA 30(b)(6)] Tr.) at 154:14 – 157:8; Dkt. #3859-7 (Colosimo Tr.) at 181:15 – 182:1; Dkt. #1969-21 (5/15/19 Rannazzisi Tr.) at 431:19 – 433:11, 448:4 – 449:3, 465:13-23; Dkt. #1969-14 (5/17/19 Prevoznik [DEA 30(b)(6)] Tr.) at 1063:3-19.

[91] Dkt. #3859-2 (Ashley Tr.) at 113:22 – 114:9 (former DEA official: "Q: Would you agree that these defendants have an obligation to keep current on both the federal and state laws and regulations associated with the dispensing of controlled substances? A: Yes, I agree. Q: They have an obligation to read and follow the regulations, true? A: Yes, I agree with that. Q: These companies have an obligation to read and know the developments in the laws and regulations, as they may be modified or changed over the years? A: I agree with that."), 119:25 – 120:10; Dkt. #3859-18 (7/12/19 Mapes Tr.) at 462:10-12 ("Q: Ignorance of law is not excuse, right? A: Right."). *Cf. Heckler v. Community Health Services of Crawford County, Inc.*, 467 U.S. 51, 63 (1984); *Wilber Nat. Bank of Oneonta, N.Y., v. U.S.*, 294 U.S. 120, 124 (1935).

[92] Dkt. #3027-32 (12/13/18 Tsipakis [HBC 30(b)(6)] Tr.) at 28:9 – 34:13, 36:10-24, 40:7-12, 54:8 – 58:4, 59:18 – 60:11, 92:8-15, 104:3-5, 107:24 – 108:7, 124:8-20, 125:19-25, 126:24 – 128:20, 137:22 – 138:4, 165:10-13, 170:11-18, 187:20-22, 188:19 – 189:3, 201:21-25, 202:7-10, 298:12 – 299:22; Dkt. #3859-7 (Colosimo Tr.) at 138:17 – 140:5, 140:6-10 ("Q: And, sir, the fact that the DEA didn't approve or endorse specific systems, that was, in fact, communicated to registrants like HBC, correct, sir? A: That is my understanding, yes."); Dkt. #3859-2 (Ashley Tr.) at 114:19 – 117:21, 134:22 – 135:4, 136:8-12 ("Q: And that corresponding responsibility is something that should be well-known to these defendant pharmacy companies ever since they first got registered, right? I imagine so, yes."); Dkt. #1959-24 (1/16/19 Chunderlik Tr.) at 27:8-14; Dkt. #1969-21 (5/15/19 Rannazzisi Tr.) at 502:5-13, 529:2-17; **Ex. 47** (12/13/18 Tsipakis Dep. Ex. 13) (2012 DEA letter to all registrants reiterating SOM duties); Dkt. #1959-18 (Carlson Tr.) at 92:20-25, 93:14-22, 94:7-11, 94:15 – 95:7; *see also supra* at fn.25 (evidence demonstrating Giant Eagle knew and understood its dispensing duties).

[93] Moreover, these inspectors were relying on information provided to them, and the GE Defendants certainly knew what information they were, and more significantly were not, providing to those inspectors. *Id.* Although they

ever explicitly told them that they were implementing their SOM systems, or their controlled substance dispensing policies and procedures, in accordance with the CSA and its regulations. *Cf. United States v. Triana*, 468 F.3d 308, 316-18 (6th Cir. 2006) (rejecting applicability of entrapment by estoppel defense where there was no evidence that any "government official ever *explicitly* told [defendant] that his actions were legal" and defendant was aware of the applicable legal requirements) (emphasis in original).

For these reasons, the GE Defendants could not have reasonably relied on any DEA or Ohio BOP inspections,[94] or the lack of any sanctions or administrative actions by those agencies, as official determinations that they were fully complying with their regulatory obligations.[95]

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claim that the inspectors could have requested whatever information they wanted (Ds' MOL, pp. 9 n.10, 25), it would not have been feasible or reasonable for those inspectors to review the relevant documentation associated with every single suspicious (or potentially suspicious) order or red flag prescription during these short, routine inspections. *Supra* at § IV.A.2.i-ii. Nor was it necessary, as that was not the purpose of those inspections. *Id*.

[94] The GE Defendants argue that both Mr. Colosimo and Mr. Rafalski testified that the GE Defendants were "entitled and expected to rely upon the favorable results of their DEA's investigations[.]" Ds' MOL, p. 19 (emphasis omitted). But the cited testimony is much more limited than the GE Defendants insinuate. *See* Dkt. #3859-7 (Colosimo Tr.) at 86:18 – 87:7 ("Q:…. [W]ouldn't you agree that it would be reasonable for the – if you do your investigation and you have a meeting with management and you say *from everything I've seen*, you meet all of the requirements, you're good to go, they should be able to rely on what you're telling them, right, that their systems, their security systems that they have in place are at least adequate, if not more than adequate, under the DEA regulations? A: I mean, *insofar as what I'm able to determine on that pre-registrant investigation*, I would agree with that.") (internal objection omitted) (emphasis added); Dkt. #3859-27 (6/10/21 Rafalski Tr.) at 79:14 – 80:5 ("Q: Okay. Now, would you agree that a registrant should be able to rely on a passing grade from the DEA and in feeling comfortable that their systems are, you know, in compliance with the DEA regulations? A: *I'm not in total agreement*. I guess it would depend on the circumstances. . . . If it's something that's clearly a simpler issue contained within the regulations, that would be something I think that a registrant could rely on more. *But if it would be more of a complex matter, I – I would not agree with you*.") (internal objection omitted) (emphasis added), 80:8 – 81:1 (discussing scenario where registrant "disclose[s] everything[,]" explains "in great detail how [its] SOM system operates[;]" and shows the inspector its vault and "walk[s] him through everything that [he] want[s] to . . . do and see": "I think you can put some reliance on that. But I don't think that – that as that DEA investigator leads, I don't think you can put your full faith that everything is perfectly correct. And I say that through my experience in some of the cases I've dealt with. Specifically, there have been issues where previous inspections had not identified any issue.") (emphasis added), 81:2-22, 82:2-13 ("Q:… [Y]ou're coming in to a registrant and you're telling them that they're okay, shouldn't they be able to rely on that? A: As I answered earlier, I generally agree with that. But there are certain areas that a registrant should – would seek a higher approval.") (internal objection omitted).

[95] Dkt. #1969-21 (5/15/19 Rannazzisi Tr.) at 466:10-22 ("Q: Well, what if they say, oh, but the DEA told us it is okay to do it this way? A: No. The DEA would not tell them to do something outside of the regulation. Q: And did you specifically warn them of this, that the DEA does not approve or otherwise endorse any specific system

Individual government agents cannot individually authorize that which the law does not sanction or permit.[96] Nor is government inaction a determination of compliance.[97] These DEA and Ohio BOP inspections certainly would not preclude either agency from pursuing administrative actions against, or otherwise sanctioning, the GE Defendants for violations of their statutory and regulatory obligations relating to the distribution and dispensing of opioids. *See, e.g.,* Dkt. #2652 (CT1 Ps' MILs) at pp. 13-16. Nor should they preclude Plaintiffs' public nuisance claims.

Because the GE Defendants had fair notice of their legal obligations, as well as the limited scope of the agency inspections, they could not have reasonably relied on those inspections, or on any government inaction, as agency determinations that their conduct was lawful.[98] As such, imposing nuisance liability based on their unlawful conduct does not violate due process. For these and other reasons, the GE Defendants' cases are distinguishable.[99]

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for reporting suspicious orders? A: Yes.") (internal objections omitted); Dkt. #3859-27 (6/10/21 Rafalski Tr.) at 81:16-22 ("[A] registrant is bound to comply with the regulations, and that's not dependent on whether or not an inspection is conducted, and an issue is not found or discovered or detailed by a diversion investigation, it doesn't relinquish the responsibilities to comply with the regulations.").

[96] *See Heckler*, 467 U.S. at 63; *Niewiadomski v. U.S.*, 159 F.2d 683, 688 (6th Cir. 1947); *U.S. v. City of Menominee, Mich.*, 727 F. Supp. 1110, 1121 (W.D. Mich. 1989); *Farmers Home Admin. v. Call*, 145 F.3d 1331, 1998 WL 246038, at *3 (6th Cir. 1998).

[97] *Cf. U.S. v. 789 Cases, More or Less, of Latex Surgeons' Gloves, an Article of Device*, 799 F. Supp. 1275, 1296-97 (D.P.R. 1992); *City of Menominee*, 727 F. Supp. at 1122; *Moran Mar. Associates v. U.S. Coast Guard*, 526 F. Supp. 335, 342 (D.D.C. 1981), *aff'd sub nom. Moran Mar. Associates Am. Waterways Operators, Inc. v. U.S. Coast Guard*, 679 F.2d 261 (D.C. Cir. 1982). There are many reasons that the DEA or Ohio BOP may have failed to act that have nothing to do with the lawfulness of the GE Defendants' conduct, including the agencies' limited resources and the GE Defendants' concealment of its unlawful conduct. *See, e.g., Christopher v. SmithKline Beecham Corp.*, 567 U.S. 142, 157 (2012) (acknowledging "that an agency's enforcement decisions are informed by a host of factors, some bearing no relation to the agency's views regarding whether a violation has occurred").

[98] Moreover, although the GE Defendants claim that they would have improved their SOM systems if the DEA had told them to, that assertion is belied by their failure to do so after receiving the 2012 DEA letter clearly reiterating their SOM obligations. *See, e.g.,* **Ex. 2** (CT1 Ps' Opp. to HBC MSJ [Dkt. #3009-1]) at pp. 2-4; **Ex. 1** (CT1 Ps' Compliance MSJ [Dkt. #3015-1] Excerpts) at pp. 132-136, 138-139; **Ex. 4** (CT1 Ps' Compliance MSJ Reply [Dkt. #3017-1] Excerpts)at pp. 50-52; *supra* at § II.B.

[99] *See F.C.C. v. Fox Television Stations, Inc.*, 567 U.S. 239, 255–58 (2012) (due process rights of television networks violated where they had no fair notice prior to FCC imposing sanctions that, in contrast to prior policy, fleeting expletives or brief shots of nudity could be actionably indecent; FCC conceded lack of notice as to non-

3. As this Court has previously recognized, there are triable issues of fact as to whether HBC's distribution activities were unlawful.

This Court has already ruled, in Track One, that there were triable issues of fact precluding summary judgment regarding the adequacy of HBC's SOM system:

> Construed in a light most favorable to Plaintiffs, the existing record presents a triable issue of fact regarding the adequacy of HBC's suspicious order monitoring system. Moreover, the evidence suggests obvious deficiencies that a layperson could plainly recognize.

Dkt. #3101 (CT1 HBC MSJ Order) at p. 4.[100] Significantly, HBC made many of the same arguments in its CT1 briefing that it makes in this case, including that summary judgment was warranted because "both the State of Ohio and the DEA licensed, inspected, and audited Giant

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repeated expletives and failed to identify anything that would have given network notice as to brief shots of nudity); *Christopher*, 567 U.S. at 157-58 (defendant did not have fair notice of Department of Labor's newly announced interpretation of regulation where, among other things, DOL had never initiated enforcement actions *against anyone in the industry* based on that interpretation); *Honda Motor Co. v. Oberg*, 512 U.S. 415, 434–35 (1994) (imposition of exemplary damages must satisfy due process to prevent arbitrary deprivation of property); *United States v. Pennsylvania Indus. Chem. Corp.*, 411 U.S. 655, 673–75 (1973) (criminal defendant should have been permitted to offer evidence at trial that "it was affirmatively misled by the responsible administrative agency into believing that the law did not apply in [the defendant's particular] situation" in order to determine whether defendant was deprived "of fair warning as to what conduct the Government intended to make criminal" in violation of the "traditional notions of fairness inherent in our system of criminal justice"); *United States v. Laub*, 385 U.S. 475, 487 (1967) (in criminal case, court noted that "[o]dinarily, citizens may not be punished for actions undertaken in good faith reliance upon authoritative assurance that punishment will not attach"); *Raley v. State of Ohio*, 360 U.S. 423, 437–39 (1959) (criminal defendants could not be convicted for exercising their privilege against self-incrimination where "Chairman of [State] Commission, who clearly appeared to be the agent of the State in a position to give such assurances" "active[ly] misle[d]" defendants that invocation of privilege was permitted); *United States v. Hoechst Celanese Corp.*, 128 F.3d 216, 219, 224, 229 (4th Cir. 1997) (defendant could not be held liable for regulatory violations that occurred at a time when defendant lacked fair notice of EPA's interpretation of the regulations, but *could* be held liable for violations that occurred after "EPA provided the company with actual notice of EPA's interpretation of the regulations"; court noted that "[g]enerally, 'ignorance of the law or a mistake of the law is no defense,' and a claim of lack of notice 'may be overcome in any specific case where reasonable persons would know that their conduct is at risk'") (internal citation omitted); *S. Appalachian Mountain Stewards v. Red River Coal Co., Inc.*, 420 F. Supp. 3d 481, 496-97 (W.D. Va. 2019) (determining whether permit shield provision of Clean Water Act (CWA) protects coal mine operator from CWA liability for discharges from underdrains where state agency "was aware of those discharges but chose not to list them in the Permit" as being subject to specific limits), *aff'd,* 992 F.3d 306 (4th Cir. 2021). As in *N.L.R.B. v. Bell Aerospace Co. Div. of Textron*, "this is not a case in which some *new* liability is sought to be imposed on individuals for past actions which were taken in *good-faith reliance* on [agency] pronouncements." 416 U.S. 267, 295 (1974) (emphasis added).

[100] The Court based its ruling on the record evidence set forth in the CT1 plaintiffs' summary judgment briefing, which as noted above (*supra* at § II.A) is incorporated by reference as if fully set forth herein.

Eagle's distribution activities and order monitoring procedures" and "[i]n all of its inspections and audits, the DEA never cited Giant Eagle for any violation—it never even recommended a material change to Giant Eagle's SOM system." Dkt. #1912-1 (CT1 HBC MSJ) at pp. 11, 16. Despite these arguments, the Court denied HBC's summary judgment motion. Dkt. #3101 (CT1 HBC MSJ Order).

In the present case, there is even more evidence supporting the Court's prior ruling. Plaintiffs' expert, James Rafalski, has analyzed HBC's SOM system, and its implementation, and determined that there was a systematic, prolonged failure by HBC to maintain effective controls against diversion of opioids into the illicit market in violation of the CSA and its implementing regulations.[101] Specifically, he opines that HBC: (1) "failed to develop and implement a SOMS that would ensure the maintenance of effective controls against diversion[;]" (2) "failed to develop a comprehensive system to monitor, detect, and report all suspicious orders of opioids placed by pharmacies in [the] Counties" and such failure was "exacerbated as there were significant timeframes when [HBC] would identify suspicious orders and still ship the orders to the respective pharmacies[;]" (3) "failed to conduct adequate due diligence on suspicious orders placed by pharmacies in [the] Counties, to determine whether the customer was engaged in diversion[;]" (4) "distributed opioids to pharmacies in [the] Counties in disproportionately excessive amounts without adequately documenting justification[;]" and (5) "failed to halt suspicious shipments of opioids to pharmacies in [the] Counties [it] knew, or should have known, were going to be diverted." Dkt. #3852-13 (Rafalski Rep.) at p. 9; *see also id.* at pp. 149-158.[102] Plaintiffs' experts

[101] Dkt. #3852-13 (Rafalski Rep.) at pp. 9, 149, 153-158; Dkt. #3859-27 (6/10/21 Rafalski Tr.) at 100:10-22, 101:19-20.

[102] *See also* Dkt. #3859-27 (6/10/21 Rafalski Tr.) at 32:17-22, 69:6 – 71:5, 87:10-17, 111:24 – 112:5 (corrected by errata), 167:6-13; **Ex. 49** (Errata to 6/10/21 Rafalski Tr.) ("Self-distributing provided Defendants with access to

have also identified a significant number of hydrocodone orders shipped to the Counties by HBC that should have been flagged as suspicious and subject to due diligence.[103]

The GE Defendants argue that Plaintiffs' "experts' reliance on a purported lack of documentation undermines Rule 702's gatekeeping function and improperly imposes on Giant Eagle the burden of *disproving* [Plaintiffs'] case." Ds' MOL, p. 27 n.28 (emphasis in original). But the case they cite is entirely distinguishable. In *Soldo v. Sandoz Pharms. Corp.*, 244 F. Supp. 2d 434 (W.D. Pa. 2003), the court held that the plaintiff's experts' causation opinions in a product liability action were inadmissible because there was no reliable scientific evidence demonstrating that the pharmaceutical drug at issue increased the risk of stroke. *Id*. at 505-513, 528-29. The court rejected the idea that an expert could conclude the drug can cause stroke "simply because there is an *absence* of evidence (*i.e.*, no studies proving [drug] cannot cause stroke as opposed to reliable scientific evidence providing that it does)[,]" noting such a conclusion would not be "grounded in reliable scientific methodology." *Id*. at 508. Thus, the plaintiff could not satisfy her "burden of proving causation [or] the reliability of her experts' testimony." *Id*. at 558.

The circumstances in the present case are completely different. Plaintiffs are not seeking

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a substantial amount of information that they were obligated to use in the maintenance of effective controls against diversion."); Dkt. #3859-28 (6/11/21 Rafalski Tr.) at 392:7-14, 461:8-16 ("Q: And when you do – and your opinion that is in your report is that from 2009, when HBC first was granted a license for Schedule 3 drugs, until hydrocodone was reclassified in 2014, during that entire period of time, Giant Eagle was not even in substantial compliance; it wasn't in compliance at all, right? A: In regards to their SOMS system, that's correct."), 462:1-4, 489:1-5, 492:10-18, 494:4-11 ("Based on my review of all the documents and information related to Giant Eagle, I was able to form an opinion that they did not meet the maintenance of effective controls to prevent diversion of controlled substances and did not have a proper Suspicious Order Monitoring System. That is a correct statement. That is what my opinion found."), 509:13-23 ("Q: And do you stand by your opinions about Giant Eagle as set forth in your report? A: Yes, I do.") (internal objection omitted), 509:24 – 510:17, 519:24 – 520:3, 520:14-18, 521:4-10.

[103] Dkt. #3852-13 (Rafalski Rep.) at pp. 46-56; Dkt. #3852-11 (5/4/21 McCann Supp. Rep.) at pp. 7-48; **Ex. 50** (McCann Dep. Ex. 5 Excerpts); Dkt. #3859-27 (6/10/21 Rafalski Tr.) at 106:25 – 107:13; **Ex. 49** (Errata to 6/10/21 Rafalski Tr.) ("While I cannot address whether any specific prescription was diverted, based upon my review and analysis of the available information, including the absence of sufficient due diligence performance by each Defendant, I do opine that the orders identified as suspicious were more likely than not diverted.").

to support a general causation opinion despite a lack of supporting scientific evidence. Instead, Mr. Rafalski has opined that in order to implement effective controls against diversion, a registrant must document the due diligence done on suspicious orders and retain such documentation.[104] The DEA has confirmed this position. Dkt. #1969-14 (5/17/19 Prevoznik [DEA 30(b)(6)] Tr.) at 987:19 – 988:9 ("A: 'Good recordkeeping is essential.' Q: Do you agree with that statement? A: Yes. Q: In DEA's experience, is the absence of documentation a fairly good indication that something didn't happen in a registrant's compliance program? A: Yes.") (internal objection omitted), 996:7-23. Yet the GE Defendants have produced almost no documentation to support their claim that due diligence was performed. Dkt. #3852-13 (Rafalski Rep.) at pp. 156-157; Dkt. #3859-28 (6/11/21 Rafalski Tr.) at 523:1-4. And this Court has previously held that "[b]ased on his experience as a DEA Diversion Investigator . . ., Rafalski may opine as to what the absence of due diligence records indicates to him." Dkt. #2494 (CT1 Rafalski Daubert Order) at p. 13. Ultimately, whether the GE Defendants performed the necessary due diligence on suspicious orders is a fact determination to be made by the jury.

4. There are triable issues of fact as to whether Giant Eagle's distribution activities through its GERX distribution facility were unlawful.

As set forth above, *by Giant Eagle's own admission*, the SOM system implemented at GERX from early 2016 through early 2017 did not fully comply with CSA regulations. *Supra* at p. 7. The record evidence supports this conclusion.

Giant Eagle was required to design and operate a system that would identify suspicious orders. 21 C.F.R. § 1301.74(b); Dkt. #2483 (CT1 CSA MSJ Order) at p. 15. Until at least early 2017, GERX continued to use the same fatally "flawed" threshold system used previously by HBC,

[104] Dkt. #3852-13 (Rafalski Rep.) at pp. 40-44; Dkt. #3859-27 (6/10/21 Rafalski Tr.) at 345:17-23, 346:4-10; Dkt. #3859-28 (6/11/21 Rafalski Tr.) at 518:2 – 519:23.

which was based on a chain-wide threshold that admittedly could lead to false negatives. *Supra* at pp. 3-4. This threshold system did not flag orders of unusual frequency or pattern. Dkt. #1959-24 (1/16/19 Chunderlik Tr.) at 201:18 – 202:4. Moreover, the threshold system was systematically ignored, with orders regularly exceeding the thresholds yet being shipped anyway. *Supra* at pp. 4- 5.

Giant Eagle was also required to report suspicious orders to the DEA when discovered. 21 C.F.R. § 1301.74(b); Dkt. #2483 (CT1 CSA MSJ Order) at p. 15. Yet in the entire history of its distribution activities (by HBC and GERX), the GE Defendants only reported two suspicious orders to the DEA, neither of which were orders placed to the GERX facility. *Supra* at fn.13. This is despite the fact that many orders, including orders from pharmacies in the Counties, were flagged by Giant Eagle's SOM system as exceeding the threshold. *Supra* at p 5.

Finally, Giant Eagle was required to halt shipment of suspicious order until and unless it conducted due diligence that reasonably dispelled the suspicion. Dkt. #2483 (CT1 CSA MSJ Order) at pp. 18-19.[105] Yet Giant Eagle failed to develop a system with the capability of stopping shipment of a suspicious order until early 2017. *Supra* at pp. 5-6. Prior to that time, any orders flagged on Giant Eagle's threshold report had already been shipped with no opportunity to conduct any due diligence prior to shipping. *Id*. And even after Giant Eagle revised its SOM system to stop suspicious orders to allow for investigation, there is little evidence this was actually done (and no evidence it was done consistently). *Supra* at pp. 6-7; Dkt. #3852-13 (Rafalski Rep.) at pp. 156-157.

Contrary to the GE Defendants' assertions,[106] Plaintiffs' expert, Mr. Rafalski, has analyzed

[105] *See also* Dkt. #3859-27 (6/10/21 Rafalski Tr.) at 70:3 – 71:5.

[106] The GE Defendants quote certain testimony of Mr. Rafalski to argue he is offering no opinions regarding GERX.

GERX's SOM system and its implementation and determined that, at least until early 2017, Giant Eagle did not comply with its CSA obligations.[107] Additionally, Plaintiffs' expert, Dr. Craig McCann, has identified thousands of orders of Schedule II & III opioids shipped from the GERX facility into the Counties that should have been flagged as suspicious. *See, e.g.,* Dkt. #3852-11 (5/4/21 McCann Supp. Rep.) at pp. 9, 12, 21, 24, 27, 30, 33, 36, 39, 42, 45, 48.

The GE Defendants argue that its GERX facility received approval from the National Association of Boards of Pharmacy ("NABP") for a Verified-Accredited Wholesale Distributors ("VAWD") certification, which demonstrates that its SOM system complied with the CSA's regulatory obligations. Ds' MOL, pp. 31-32. But as with the DEA inspections discussed above (*supra* at § IV.A.2.i), there is no evidence that the NABP analyzed Giant Eagle's *implementation* of its SOM system. As Mr. Catizone explained in his deposition, VAWD accreditation focuses primarily on compliance with the Food, Drug and Cosmetic Act, with only a "tertiary review of whether or not they're compliance with [the] Controlled Substances Act." Dkt. #3859-4 (6/15/21 Catizone Tr.) at 119:16-19; *see also id.* at 118:15-23. The NABP will merely "look at [the applicant's] policies and procedures, and then they may pull an invoice to do a random audit." *Id*.

Ds' MOL, p. 31. However, they fail to mention that Mr. Rafalski issued an errata to his deposition, making clear that he was offering opinions on GERX-related conduct to "at least 2017." **Ex. 49** (Errata to 6/10/21 Rafalski Tr.) ("Each reference to '2016' is replaced with 'at least 2017.' Additionally, as is addressed in my report, despite adjustments made to Giant Eagle's SOMs policies in 2017, Giant Eagle's SOM system did not result in any reported suspicious orders nationwide. See pages 156-157. Through at least 2017, the system did not flag orders above the internal thresholds until after the orders were shipped. See page 157-158."). This is entirely consistent with the opinions set forth in his expert report. Dkt. #3852-13 (Rafalski Rep.) at pp. 9, 149-158.

[107] Dkt. #3852-13 (Rafalski Rep.) at pp. 9, 149--158; Dkt. #3859-27 (6/10/21 Rafalski Tr.) at 32:17-22, 69:6 – 71:5, 87:10-17, 100:10-22 (corrected by errata), 101:14-25 (corrected by errata); **Ex. 49** (Errata to 6/10/21 Rafalski Tr.); Dkt. #3859-28 (6/11/21 Rafalski Tr.) at 489:1-5, 494:4-11 ("Based on my review of all the documents and information related to Giant Eagle, I was able to form an opinion that they did not meet the maintenance of effective controls to prevent diversion of controlled substances and did not have a proper Suspicious Order Monitoring System. That is a correct statement. That is what my opinion found."), 509:13-23 ("Q: And do you stand by your opinions about Giant Eagle as set forth in your report? A: Yes, I do.") (internal objection omitted), 509:24 – 510:17.

at 119:21-25. The policy that Giant Eagle submitted to the NABP was the 2015 version of its "Inventory Control – Suspicious Order Policy." **Ex. 51** (Chunderlik 1/16/19 Dep. Ex. 14). This policy was two pages, provided minimal detail, and claimed that suspicious orders "are blocked" and investigated. *Id*. at HBC_MDL00169476-9477. As discussed above, this was not true until at least early 2017. *Supra* at pp. 5-6.

5. There are triable issues of fact as to whether Giant Eagle's dispensing activities were unlawful.

As Plaintiffs' pharmacy expert, Carmen Catizone, explained, Giant Eagle's corporate oversight of its pharmacies should: (1) "incorporate top-down compliance programs using data readily available to [Giant Eagle] to guard against diversion[;]" (2) "support, and not impede, pharmacists in complying with laws and regulations related to the dispensing of controlled substances[;]" and (3) "set patient care and integrity expectations and provide tools for pharmacists to exercise practices to adhere to appropriate laws, regulations, and pharmacy standards of care in dispensing controlled substances."[108] Giant Eagle "and [its] pharmacists have a corresponding responsibility to only fill prescriptions for controlled substances that are issued for a legitimate medical purpose by an individual practitioner acting in the usual course of his/her professional practice."[109] Both Giant Eagle and its pharmacists were required "to check for and conclusively

[108] Dkt. #3852-3 (5/19/21 Catizone Supp. Rep.) at p. 3. *See also id*. at pp. 9-13, 105; Dkt. #3859-4 (6/15/21 Catizone Tr.) at 166:9-15, 175:9 – 176:25; Dkt. #3859-5 (6/16/21 Catizone Tr.) at 350:17 – 352:7, 352:25 – 355:20, 356:12-23, 357:9 – 358:13, 382:25 – 383:8, 383:13 – 385:14, 409:1 – 411:19, 449:16 – 450:2, 451:18 – 453:4. *See also* Dkt. #3859-2 (Ashley Tr.) at 123:9 – 124:16, 134:2-9 ("Q: And in terms of the pharmacy companies obligation to establish appropriate controls to guard against diversion, it would be reasonable to expect the pharmacies to access their own databases to look for red flags, right? A: That is reasonable, yes.") (internal objections omitted)

[109] Dkt. #3852-3 (5/19/21 Catizone Supp. Rep.) at p. 4. *See also id.* at p. 10; Dkt. #3859-4 (6/15/21 Catizone Tr.) at 161:21 – 162:6; Dkt. #3859-5 (6/16/21 Catizone Tr.) at 355:6-9, 355:18-20, 387:18-21; Dkt. #3859-2 (Ashley Tr.) at 134:22 – 135:4, 135:22 – 136:19.

resolve red flags of possible diversion prior to dispensing [controlled] substances."[110] Giant Eagle cannot ignore prescription information it has that would be useful in determining whether a particular prescription is invalid.[111] Finally, it is critical that the findings and outcome of any red flag investigation be documented and retained.[112]

After reviewing Giant Eagle's "policies, procedures and practices as well as the dispensing data that [it] provided and which demonstrated that [Giant Eagle] dispensed thousands of controlled substances in the presence of known red flags[,]" Mr. Catizone concluded that Giant Eagle's "dispensing of prescriptions without the resolution of obvious and known red flags did not

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[110] Dkt. #3403 (CT3 MTD Order) at p. 22; Dkt. #3859-4 (6/15/21 Catizone Tr.) at 158:19 – 159:12, 176:16-25; Dkt. #3859-5 (6/16/21 Catizone Tr.) at 355:6-20, 398:21 – 400:9, 443:13 – 444:16, 455:9 – 456:21, 522:15 – 523:11, 523:20-24, 524:9-13. In their motion, the GE Defendants claim that Mr. Rafalski "agreed that a pharmacy 'doesn't need to do any further due diligence' when it is dispensing 'a [couple hundred] dosage units a month.'" Ds' MOL, p. 14 (quoting Dkt. #3859-27 (6/10/21 Rafalski Tr.) at 149:15 – 150:1). This is a complete mischaracterization of his testimony. First, Mr. Rafalski's opinions in this case relate to Defendants' *distribution* conduct. Dkt. #3852-13 (Rafalski Rep.). Through their selective quotation of his testimony, the GE Defendants imply that Mr. Rafalski was opining on the due diligence that should or should not be conducted by pharmacies when analyzing red flag prescriptions. Not so. In actuality, Mr. Rafalski was discussing certain advice that he had previously given to a Purdue employee on signs to look for when investigating potentially problematic pharmacies on behalf of Purdue. Dkt. #3859-27 (6/10/21 Rafalski Tr.) at 143:15-21, 145:1 – 149:14. The GE Defendants also fail to provide the entirety of his answer: "Q: Right. And conversely you are telling Mr. Crowley that if the pharmacy has less than a thousand dosage units per month, and especially substantially less, then that shouldn't raise his eyebrow, that would not be a red flag, and he doesn't need to do any further due diligence? A: *I don't think it would completely preclude it*, but *generally speaking* if it was much less, a hundred couple dosage units a month, I would tend to agree with that statement." *Id.* at 149:15 – 150:1 (internal objection omitted) (emphasis added).

[111] Dkt. #3403 (CT3 MTD Order) at p. 25; Dkt. #3499 (CT3 Reconsideration Order) at p. 7; Dkt. #3859-4 (6/15/21 Catizone Tr.) at 177:9 – 178:2; Dkt. #3859-5 (6/16/21 Catizone Tr.) at 358:1-13.

[112] As Mr. Catizone explains: "Documentation related to the dispensing of controlled substances is a critical component of any system or program. Documentation identifies critical factors, such as red flags, whether the pharmacist resolved the red flag(s), and information alerting to the occurrence or possibility of diversion. It also provides proactive direction to other pharmacists presented with the prescription going forward." Dkt. #3852-3 (5/19/21 Catizone Supp. Rep.) at p. 10; *see also id.* at pp. 60-61. *See also* Dkt. #3859-4 (6/15/21 Catizone Tr.) at 71:12-14, 164:7 – 165:2 (explaining that the failure to document violates 21 C.F.R. § 1306.04 and applicable standards of care), 219:1-11, 219:23 – 220:3, 327:16 – 329:8, 329:18 – 330:25, 331:19 – 332:3, 332:23 – 333:21; Dkt. #3859-5 (6/16/21 Catizone Tr.) at 355:9-17, 405:23 – 406:17, 407:15 – 408:17, 436:6-14 (discussing importance of documentation; "[N]o pharmacist I'm aware of works 24 hours a day, seven days a week, so if there are other pharmacists in the pharmacy that didn't have that relationship with the patient, and didn't know that patient history, documentation in that patient profile, or with that prescription, would help that pharmacist understand and realize those red flags had been resolved . . ."), 438:3-8, 523:13-24, 524:9-13.

meet the required pharmacy practice and regulatory standards for dispensing controlled substances resulting in a widespread failure to maintain effective controls to guard against the diversion of controlled substances."[113]

Mr. Catizone's opinions are fully supported by the evidence set forth above. *Supra* at § II.C. Specifically, the evidence supports Mr. Catizone's conclusions[114] that Giant Eagle: (1) "failed to timely implement and apply necessary controlled substance diversion policies across [its] pharmacy stores"[115] (*supra* at § II.C.1); (2) "failed to monitor and enforce the policies across their pharmacy stores" once they were created (*supra* at § II.C.3); (3) "possessed dispensing data and other information collected at a corporate level" that "could and should have been utilized by [Giant Eagle] to prevent diversion" (*supra* at § II.C 2); (4) failed to provide its pharmacists "with the data and tools necessary to fulfill their corresponding responsibility duties, including but not limited to, providing their pharmacists with access to dispensing data as well as the analysis of that data as it relates to red flags of diversion"[116] (*supra* at § II.C 2); (5) implemented "employment

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[113] Dkt. #3852-3 (5/19/21 Catizone Supp. Rep.) at p. 4. *See also id*. at pp. 3, 10, 30, 52-54, 58, 60-62, 69-71, 89-90, 99, 104-105; Dkt. #3859-4 (6/15/21 Catizone Tr.) at 160:20 – 162:14, 163:3 – 165:2, 166:9-15, 180:1 – 183:2, 185:12 – 186:8; Dkt. #3859-5 (6/16/21 Catizone Tr.) at 358:15-22, 409:1-12, 412:13-21, 443:13 – 444:16, 463:9 – 464:6.

[114] Dkt. #3852-3 (5/19/21 Catizone Supp. Rep.) at pp. 3-4, 10, 12-13, 32-52, 54, 70, 95-96, 104-05.

[115] *See also, e.g.,* Dkt. #3852-3 (5/19/21 Catizone Supp. Rep.) at p. 90 ("Defendants' policies for years failed to require that pharmacists check OARRS before dispensing opioid prescriptions, despite clear recognition of the critical role that such PDMPs play in fighting diversion."); Dkt. #3859-5 (6/16/21 Catizone Tr.) at 382:25 – 383:8 (Defendants should have had blanket refusal to fill policies), 383:13 – 385:14, 386:9-24, 387:11 – 388:25, 465:8-20, 477:2-14, 480:7 – 482:2.

[116] Mr. Catizone further explains that Giant Eagle "should have had systems and programs in place to detect, report and store this information in a format that could be easily retrieved and reviewed by corporate headquarters and its pharmacists. If the information were stored in this format, it could have been used to identify patients and potentially their prescribers engaged in diversion." Dkt. #3852-3 (5/19/21 Catizone Supp. Rep.) at p. 54. *See also* Dkt. #3859-4 (6/15/21 Catizone Tr.) at 254:3-14; Dkt. #3859-5 (6/16/21 Catizone Tr.) at 350:17 – 352:7. As this Court recognized, many red flags "include indicia that would be very difficult, if not impossible, for a human pharmacist to identify consistently absent a system to aggregate, analyze, and provide feedback to the pharmacist after the prescription." Dkt. #3403 (CT3 MTD Order) at p. 23.

evaluation policies," "performance metrics[,] and pharmacy operations financial incentives [that] hampered the ability of [its] pharmacists . . . to maintain effective controls to guard against the diversion of [opioids] through [its] pharmacies[,]" in violation of relevant laws, regulations, and standards of care[117] (*supra* at § II.C.3); and (6) "filled thousands of prescriptions presenting red flags without evidence of resolving those red flags" (*supra* at § II.C.4).[118] The evidence further demonstrates that Giant Eagle's failures resulted in "the diversion of significant quantities of . . . opioids[ ] outside the closed distribution and dispensing system for controlled substances."[119] *Supra* at § II.C.5; *infra* at § IV.B.

B. THE GE DEFENDANTS' DISTRIBUTION AND DISPENSING PRACTICES WERE A PROXIMATE CAUSE OF THE PUBLIC NUISANCE IN THE COUNTIES.

The evidence establishes, or at least creates a dispute of material fact, that the GE Defendants' blatant disregard of their lawfully required distribution and dispensing duties substantially contributed to the opioid epidemic and its resulting harms in the Counties. As

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[117] "Corporate performance metrics focused on increasing dispensing of prescriptions, increasing sales, and lowering customer wait times can place pharmacists in conflict with legal requirements such as corresponding responsibility. Emphasis is placed on meeting the performance metrics and directed away from the due diligence needed to properly evaluate and assess a prescription's appropriateness and validity." Dkt. #3852-3 (5/19/21 Catizone Supp. Rep.) at pp. 95-96. *See also id.* at p. 96 ("In the usual and customary practice of pharmacy such arbitrary metrics [like 20 minute wait times] do not allow sufficient time for the pharmacist to complete all the necessary procedures required to assess the appropriateness and validity of a prescription and safely dispense the medication."), pp. 100-104 ("A number of national and international professional pharmacy and public health organizations have called for restrictions or an end to performance metrics that focus on high volume and speed because they cause distractions, impair professional judgment, and jeopardize patient safety and public health."); Dkt. #3859-4 (6/15/21 Catizone Tr.) at 312:7-12.

[118] As explained in greater detail below (*infra* at § IV.C), discovery regarding Giant Eagle's purported due diligence on red flag prescriptions is not yet complete, and, for that reason, the GE Defendants' motion should be denied or deferred under Federal Rule of Civil Procedure 56(d). One would reasonably assume, however, that if Giant Eagle's notes field information demonstrated that its pharmacists were conducting the necessary due diligence, it would have attached such evidence to its motion. It did not.

[119] Dkt. #3852-3 (5/19/21 Catizone Supp. Rep.) at p. 4; *see also id.* at pp. 52 (stating "the volume of red flagged prescriptions dispensed in these [C]ounties is unreasonable"), 104-05; Dkt. #3859-4 (6/15/21 Catizone Tr.) at 160:20-23 ("Q…. Is it your opinion that each of the prescriptions identified by each of your red flags should not have been filled? A: Yes, sir, it is."), 160:24 – 162:14, 174:3-22; Dkt. #3859-5 (6/16/21 Catizone Tr.) at 419:9-17, 420:16 – 421:11.

explained below, Plaintiffs present sufficient proof establishing that Defendants'—including the GE Defendants'—failures were a foreseeable, substantial factor in causing opioid over-supply in Plaintiffs' communities, which in turn led to massive opioid-related harms. This is sufficient evidence to raise at least a disputed issue of material fact to be resolved at a trial.

When multiple wrongdoers contribute to a combined harm, the plaintiff must show that each defendant's conduct was a substantial factor in producing the harm. *See Pang v. Minch*, 559 N.E.2d 1313, 1324 (Ohio 1990). The threshold inquiry is whether the defendant's wrongful conduct had "a substantial as distinguished from a merely negligible effect . . ." RESTATEMENT (SECOND) OF TORTS § 431, cmt. b (1965). Moreover, "[i]f a particular act might be expected to cause a particular result and, if that result has in fact followed, the conclusion may be justified that the causal relation exists." *Id.* at § 433B, cmt. b; *see also* Dkt. #2561 (CT1 Causation MSJ Order) at p. 6 ("Because Plaintiffs have presented evidence that shows they have suffered the sort of injury that would be an expected consequence of the alleged wrongful conduct, Plaintiffs have made a sufficient showing to withstand summary judgment on this issue.").

Ultimately, questions of proximate cause are typically left to the trier of fact. *See, e.g.*, Dkt. #3403 (CT3 MTD Order) at p. 32 ("Ohio law instructs that proximate cause is ordinarily a question of fact for the jury.") (citing *Brondes Ford, Inc. v. Habitec Sec.*, 38 N.E.3d 1056, 1086 (Ohio Ct. App. 2015)); Dkt. #3579 (CT3 Apportionment Order) at pp. 3-4 ("[T]he quintessential questions ***for the jury*** in this case are: (i) whether a public nuisance exists; and (ii) if so, was any defendant a substantial factor in causing it?") (emphasis in original).

Applying this well-established law, this Court has previously denied a similar summary judgment motions brought by distributor and pharmacy defendants, *including HBC*, in Track One with respect to causation for their distribution conduct. There, the Court concluded that, based on:

> the massive increases in the supply of prescription opioids into the *Track One* Counties, combined with evidence that suggests a complete failure by the Distributors and Pharmacies to maintain effective controls against diversion, a factfinder could reasonably infer these failures were a substantial factor in producing the alleged harm suffered by Plaintiffs.

Dkt. #2561 (CT1 Causation MSJ Order) at p. 9. The Court has also denied summary judgment motions brought by other arguably *de minimis* distributors of opioids (including chain pharmacies), including one that shipped "only 0.03% of opioids sold in Summit County between 2006 and 2014." Dkt. #2559 (CT1 *De Minimis* MSJ Order) at p. 3. In so ruling, the Court noted that "even a very small proportional contribution by one of numerous defendants could equate with a rather large and substantial absolute quantity, both in monetary terms and in terms of the consequent harms." *Id.* at p. 5; *see also* Dkt. #3101 (CT1 HBC MSJ Order) at p. 5 (finding same in rejecting HBC's individual summary judgment motion).

Plaintiffs' evidence here is equally, if not more, compelling than it was in Track One. As explained above, Plaintiffs present expert testimony as well as individualized and circumstantial evidence demonstrating that Giant Eagle failed to institute adequate (and lawfully required) anti-diversion policies with respect to both their dispensing and distribution activities. *Supra* at §§ II, IV.A.3-5. As Plaintiffs' expert Mr. Rafalski opines with respect to the GE Defendants' distribution conduct: "Giant Eagle failed to maintain effective control against diversion of prescription opiates into the illicit market." Dkt. #3852-13 (Rafalski Rep.) at pp. 149, 153-158. Plaintiffs' other expert, Dr. Catizone, opines that while Giant Eagle maintained dispensing data which could and should have been utilized to prevent diversion, it failed to do so. Dkt. #3852-3 (5/19/21 Catizone Supp. Rep.) at pp. 70-71, 89-90. *See also* Dkt. #3852-9 (4/15/21 Malone Rep.) at pp. 4-8 (finding that Giant Eagle had access to data that could have been used to reduce the inappropriate dispensing of opioids).

Plaintiffs have also offered considerable expert testimony that Giant Eagle' distribution and dispensing failures led directly to an astonishingly high percentage of suspicious orders that were shipped, and red flag prescriptions that were dispensed, without proper investigation, which in turn led to extensive diversion of prescription opioid drugs in Plaintiffs' communities. First, analyzing ARCOS data and Defendants'—including the GE Defendants'—own policies, Plaintiffs' economist expert, Dr. McCann quantifies the magnitude of suspicious orders that would have been identified if Giant Eagle had adequate anti-diversion distribution practices. Dkt. #3852-10 (4/16/21 McCann Rep.) at pp. 2-6. According to Dr. McCann, HBC should have identified as many as 68,457 suspicious distribution transactions in Trumbull County, and 37,921 in Lake County from 2006-2014. *Id.* at pp. 117-18. Additionally, Dr. McCann finds that Giant Eagle should have identified thousands more suspicious distribution transactions from its GERX facility into the Counties. Dkt. #3852-11 (5/4/21 McCann Supp. Rep.) at pp. 9, 12, 21, 24, 27, 30, 33, 36, 39, 42, 45, 48.[120] Dr. McCann also determines that from 2006 through 2014, as many as 95.2% MME (milligrams morphine equivalent) in Lake County and 96.4% MME in Trumbull County should have been flagged as suspicious by distributors. Dkt. #3852-10 (4/16/21 McCann Rep.) at pp. 94-97. Similarly, from 2016 through 2017, as many as 97.7% MME in Lake County and 93.9% of MME in Trumbull County should have been flagged as suspicious by distributors. Dkt. #3852-11 (5/4/21 McCann Supp. Rep.) at pp. 37, 40.

Next, applying well-accepted dispensing flagging criteria to Giant Eagle's own dispensing data, Dr. McCann opines that a large percentage of prescriptions dispensed by Giant Eagle in the

[120] Dr. McCann's Supplemental Report applies the flagging algorithms to the processed ARCOS data supplemented with the missing transactions found in Defendants' transactional data. That report considered transactions from 2000 to 2019, which includes those shipped by the HBC facility (2009-2014) and those shipped by the GERX facility (2016-2019).

Counties during the relevant time period should have been flagged as suspicious and investigated. Dkt. #3852-12 (5/19/21 McCann Second Supp. Rep.) at pp. 3-4, 6, 10; *see also* Dkt. #3852-10 (4/16/21 McCann Rep.) at pp. 119-120, 126-131, 150-156. These failures were significant—from 2006-2019, Giant Eagle's pharmacies in Trumbull and Lake Counties dispensed a total of 27.3 and 16.8 million dosage units of opioids, respectively. Dkt. #3852-10 (4/16/21 McCann Rep.) at pp. 126-129.

Plaintiffs' experts in epidemiology, healthcare, economics, and addiction next establish that this over-supply of prescription opioids led to diversion and causally correlates to an increased rate of overdose deaths, overdoses, and other harms in Plaintiffs' communities. Plaintiffs' expert, Dr. Anna Lembke, a psychiatrist and addiction specialist, describes how the "[i]ncreased supply" of opioids in Plaintiffs' jurisdictions, "contributed to more diversion of prescription opioids" in the Counties. Dkt. #3852-8 (Lembke Rep.) at p. 269. Plaintiffs' expert and epidemiologist Dr. Keyes similarly opines that "[t]he driving force in increasing opioid-related morbidity and mortality was, and continues to be, access to and wide-spread availability of opioids." Dkt. #3852-7 (Keyes Rep.) at p. 5. Dr. Cutler, another Plaintiff economist expert, models and computes the percentage of certain specific harms in Plaintiffs' jurisdictions that would have been avoided in the absence of Defendants' distribution misconduct (Dkt. #3852-4 (4/16/21 Cutler Rep.) at pp. 104-26) and dispensing misconduct (*id*. at pp. 128-37). *See also* Dkt. #3852-5 (4/21/21 Supplement to Cutler Rep.); Dkt. #3852-6 (5/19/21 Supplement to Cutler Rep.).

Indeed, the influx of suspicious opioid orders into the Counties (and the resulting harms) as a result of lax anti-diversion policies is *exactly* the result Congress intended to avoid when enacting the CSA, and when DEA adopted its implementing regulations. As a 2007 letter from DEA to Defendants states: "*even just one distributor that uses its DEA registration to facilitate*

diversion can cause enormous harm." **Ex. 47** (12/13/18 Tsipakis Dep. Ex. 13) at ABDCMDL00269692 (emphasis added); *see also Masters Pharmaceuticals, Inc.*; Decision and Order, 80 FR 55418-01, 55475 (D.E.A. Sept. 15, 2015), *aff'd by Masters Pharm., Inc. v. Drug Enf't Admin*., 861 F.3d 206 (D.C. Cir. 2017) (CSA's "core purposes" is to "prevent prescription drug abuse and the diversion of drugs to persons who seek to abuse them.").

Likewise, the Supreme Court has long recognized the inherent causal relationship between diversion of opioids and harm to the public. *See Direct Sales Co. v. United States*, 319 U.S. 703, 710-11 (1943) ("The difference between sugar, cans, and other articles of normal trade, on the one hand, and narcotic drugs, machine guns and such restricted commodities, on the other, aris[es] from the latters' inherent capacity for harm and from the very fact they are restricted . . . ."). Thus, it was entirely expected, foreseeable, and foreseen by the GE Defendants that failing to employ sufficient distribution and dispensing practices would cause significant diversion, leading to opioid abuse and related harms. Dkt. #2561 (CT1 Causation MSJ Order) at p. 9 (if expected consequence of action occurs, conclusion that the causal relation exists is justified). As Plaintiffs' experts establish, controls against diversion—if used—would have worked. Instead, the GE Defendants sat on their hands while orders and prescriptions they knew to be suspicious poured into the Counties.

The GE Defendants first claim that Plaintiffs' causation theories are deficient because Plaintiffs "are explicitly not claiming that any specific pill distributed, or prescription filled, by Giant Eagle actually caused any harm to any individual or county." Ds' MOL, p. 29. But Plaintiffs need not present granular information on a patient-by-patient, prescription-by-prescription, shipment-by-shipment, or medical claim-by-medical claim basis to demonstrate that Giant Eagle's conduct caused a public nuisance. Dkt. #2561 (CT1 Causation MSJ Order) at p. 8 ("[T]he Court

finds Plaintiffs' aggregate proof of causation sufficient to overcome summary judgment."). As explained above, several prominent economists and public health experts demonstrate the causal chain. Evidence from the GE Defendants themselves establishes intentional and negligent conduct that would be expected to cause, and indeed did cause, and continues to cause, the Counties' injuries and the current public nuisance. As the Court determined in Track One, this evidence allows an inference of causation. *Id*.

The GE Defendants also argue—as Defendants, including HBC, argued in Track One—that it did not cause the entire harm and that Plaintiffs have not apportioned the damages between each defendant's wrongful conduct and what it describes as other "major" contributing factors to diversion and the Counties' opioid crisis. Ds' MOL, p. 31. However, as this Court already found, this does not negate causation. Rather, that argument is related to the separate and distinct issue of apportionment, if any, of the total damages, an issue not raised by any of the pending motions before this Court. Dkt. #2561 (CT1 Causation MSJ Order) at p. 6, n. 5 ("'The reason for the exceptional rule placing the burden of proof as to apportionment upon the defendant or defendants is the injustice of allowing a proved wrongdoer who has in fact caused harm to the plaintiff to escape liability merely because the harm which he has inflicted has combined with similar harm inflicted by other wrongdoers . . .'") (citation omitted). And, as Prosser and Keeton explain:

> Once it is determined that the defendant's conduct has been a cause of some damage suffered by the plaintiff, a further question may arise as to the portion of the total damage sustained which may properly be assigned to the defendant, as distinguished from other causes. The question is primarily not one of the fact of causation, but of the feasibility and practical convenience of splitting up the total harm into separate parts which may be attributed to each of two or more causes.

Prosser and Keeton, Law of Torts § 52, p. 345 (5th ed. 1984) (emphasis added). *See also People v. ConAgra Grocery Products Co*., 17 Cal.App.5th 51, 108 (Cal. App. 2017) ("[T]he fact that the

remediation plan does not apportion liability between defendants does not infect the court's causation finding.").

Plaintiffs have ample evidence, to establish, at the very least, a genuine issue of material fact on causation. The law does not permit the GE Defendants to hide behind the fact that they are part of a group of multiple wrongdoers. To find otherwise would result in a severe injustice and the GE Defendants' arguments should be rejected.

C. ADDITIONALLY AND/OR ALTERNATIVELY, THE GE DEFENDANTS' MOTION WITH RESPECT TO PLAINTIFFS' DISPENSING-BASED CLAIMS SHOULD BE DENIED OR DEFERRED PURSUANT TO RULE 56(D).

To the extent the Court is not inclined to deny summary judgment outright with respect to Plaintiffs' dispensing-related nuisance claims based on the evidence set forth herein (or pursuant to Rule 56(d)(1)), Plaintiffs request that the Court defer any such determination until discovery relating to Giant Eagle's due diligence of red flag prescriptions is complete. FED. R. CIV. P. 56(d). Specifically, Giant Eagle has yet to complete its production of the notes fields associated with the randomly-selected red flag prescriptions, as ordered by this Court. *See* Declaration of Jeff Gaddy ("Gaddy Decl."), filed contemporaneously herewith, at ¶¶ 2-13. Plaintiffs' experts cannot analyze this information until this production is complete. *Id*. at ¶ 14. The Court has already ruled that once Defendants certify that they have completed production of their notes field information, Plaintiffs' experts will have ten days to supplement their expert reports to address this new information. Dkt. #3735 (Second Revised CT3 CMO) at p. 2. Plaintiffs should be permitted the same amount of time to supplement their summary judgment opposition with this evidence and expert analysis.

The entire purpose of Rule 56(d) is to ensure plaintiffs have had a full opportunity to conduct discovery to be able to successfully defeat a summary judgment motion. *Doe*, 928 F.3d

at 490. The notes field evidence at issue is directly relevant to the question of whether Giant Eagle performed sufficient due diligence on red flag prescriptions. Gaddy Decl. at ¶ 2. Plaintiffs expect that this evidence will refute Giant Eagle's self-serving statements that it and its pharmacists conducted the due diligence necessary to resolve red flags before dispensing prescription opioids. *See, e.g.,* Ds' MOL, p. 28. Although Giant Eagle now takes the position that documentation of due diligence was not explicitly required under the CSA and its implementing regulations, Plaintiffs' experts have explained that documentation of due diligence is a necessary aspect of implementing effective controls against diversion. *Supra* at fn.112.

Plaintiffs moved to compel production of this discovery in early 2021 and have been diligent in pursuing its production. Gaddy Decl. at ¶¶ 2-3, 10-11. Defendants, in turn, have fought tooth and nail to avoid having to produce any notes field information. *Id*. at ¶¶ 2-5. Ultimately, on May 10, 2021, the Court ordered all Defendants, including Giant Eagle, "to produce notes fields data for 200 prescriptions per Pharmacy Defendant per year from 2010-2019 to be randomly selected from the universe of red flagged prescriptions Plaintiffs choose to use at trial." Dkt. #3726 (Amended Red Flag Order). Over three months later, Giant Eagle has only produced 1,551 documents. Gaddy Decl. at ¶¶ 7-9. Moreover, Giant Eagle has yet to produce the data necessary for Plaintiffs to link the notes field discovery to specific red flag prescriptions. *Id*. at ¶¶ 11-13. Giant Eagle's counsel recently informed Plaintiffs that Giant Eagle "is aiming to complete the production this month or in early September[,]" and that it is "looking into ensuring that our data productions can be linked to each randomly selected prescription" and "endeavoring to provide some type of overlay to connect hard copy prescriptions to [each randomly selected prescription]." *Id*. at ¶ 12. The ability of Plaintiffs' experts to analyze Giant Eagle's notes field production is

hindered due to the production being incomplete and the produced materials not being linked to any particular red flagged prescription. *Id*. at ¶ 14.

Because Plaintiffs will not have this important discovery before their opposition to the GE Defendants' summary judgment motion is due, the motion should be denied or, alternatively, any ruling on the motion related to Plaintiffs' dispensing-based claims should be deferred until Plaintiffs have had the opportunity to supplement their opposition with the notes field evidence and any related expert analysis. FED. R. CIV. P. 56(d)(1).

V. CONCLUSION

For the foregoing reasons, Plaintiffs request that the GE Defendants' motion for summary judgment be denied in its entirety. Additionally and/or alternatively, Plaintiffs request that the Court defer ruling on the GE Defendants' motion until Plaintiffs have had the opportunity to supplement their opposition with evidence relating to Giant Eagle's as-yet-to-be-produced notes field discovery.

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Respectfully submitted,

/s/ Jayne Conroy
Jayne Conroy
SIMMONS HANLY CONROY
112 Madison Avenue, 7th Floor
New York, NY 10016
(212) 784-6400
(212) 213-5949 (fax)
jconroy@simmonsfirm.com

/s/ Joseph F. Rice
Joseph F. Rice
MOTLEY RICE LLC
28 Bridgeside Blvd.
Mt. Pleasant, SC 29464

(843) 216-9000
(843) 216-9290 (Fax)
jrice@motleyrice.com

Paul T. Farrell, Jr., Esq.
FARRELL & FULLER LLC
1311 Ponce de Leone Ave., Suite 202
San Juan, PR 00907
(304) 654-8281
paul@farrellfuller.com

Plaintiffs' Co-Lead Counsel

W. Mark Lanier
LANIER LAW FIRM
10940 W. Sam Houston Pkwy N., Ste 100
Houston, TX 77064
(713) 659-5200
(713) 659-2204 (Fax)
wml@lanierlawfirm.com

Trial Counsel

/s/ Peter H. Weinberger
Peter H. Weinberger (0022076)
SPANGENBERG SHIBLEY & LIBER
1001 Lakeside Avenue East, Suite 1700
Cleveland, OH 44114
(216) 696-3232
(216) 696-3924 (Fax)
pweinberger@spanglaw.com

Plaintiffs' Liaison Counsel

Frank L. Gallucci
PLEVIN & GALLUCCI CO., L.P.A.
55 Public Square, Suite 222
Cleveland, OH 44113 (216)
861-0804
(216) 861-5322 (Fax)
FGallucci@pglawyer.com

Hunter J. Shkolnik
NAPOLI SHKOLNIK
360 Lexington Ave., 11th Floor

New York, NY 10017 (212)
397-1000
(646) 843-7603 (Fax)
hunter@napolilaw.com

Counsel for Plaintiffs Lake County and Trumbull County, Ohio

CERTIFICATE OF SERVICE

I HEREBY CERTIFY that on this 29th day of December 2021, I have electronically filed the foregoing with the Clerk of Court using the CM/ECF System. Copies will be served upon counsel of record by, and may be obtained through, the Court's CM/ECF System.

/s/ Anthony D. Irpino
Anthony D. Irpino